

PART 70 SIGNIFICANT SOURCE MODIFICATION OFFICE OF AIR MANAGEMENT

**Eli Lilly and Company, Tippecanoe Laboratories
1650 Lilly Road
Shadeland, Indiana 47909**

(herein known as the Permittee) is hereby authorized to construct and operate subject to the conditions contained herein, the emission units described in Section A (Source Summary) of this approval.

This approval is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Source Modification No.: 157-11031-00006	
Issued by: Paul Dubenetzky, Branch Chief Office of Air Management	Issuance Date:

TABLE OF CONTENTS

A SOURCE SUMMARY

- A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]
- A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)]
- A.3 Part 70 Permit Applicability [326 IAC 2-7-2]

B GENERAL CONSTRUCTION CONDITIONS

- B.1 Permit No Defense [IC 13]
- B.2 Definitions [326 IAC 2-7-1]
- B.3 Effective Date of the Permit [IC13-15-5-3]
- B.4 Revocation of Permits [326 IAC 2-1.1-9(5)][326 IAC 2-7-10.5(i)]
- B.5 Significant Source Modification [326 IAC 2-7-10.5(h)]

C GENERAL OPERATION CONDITIONS

- C.1 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)] [326 IAC 2-7-6(1) and (6)]
- C.2 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]
- C.3 Opacity [326 IAC 5-1]
- C.4 Operation of Equipment [326 IAC 2-7-6(6)]

Testing Requirements [326 IAC 2-7-6(1)]

- C.5 Performance Testing [326 IAC 3-6][326 IAC 2-1.1-11]

Compliance Monitoring Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

- C.6 Compliance Monitoring [326 IAC 2-1.1-11]
- C.7 Pressure Transmitter Specifications

Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

- C.8 Compliance Monitoring Plan - Failure to Take Response Steps [326 IAC 2-7-5][326 IAC 2-7-6]
- C.9 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5]

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

- C.10 Monitoring Data Availability [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)]
- C.11 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]
- C.12 General Reporting Requirements [326 IAC 2-7-5(3)(C)]

D.1 FACILITY OPERATION CONDITIONS -

One (1) general process tank, designated as tank 24

- D.1.1 PSD Minor Limit [326 IAC 2-2] [40 CFR 52.21]
- D.1.2 Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing [326 IAC 8-5-3]
- D.1.3 Leak Detection and Repair Requirements [326 IAC 20] [40 CFR Part 63, Subparts H & I]
- D.1.4 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

Compliance Determination Requirements

- D.1.5 Testing Requirements [326 IAC 2-7-6(1),(6)][326 IAC 2-1.1-11]
- D.1.6 VOC Emissions

Compliance Monitoring Requirements [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]

- D.1.7 Parametric Monitoring
- D.1.8 40 CFR Part 63, Subpart H and I (National Emissions Standard for Hazardous Air)
- D.1.9 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical)

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.1.10 Record Keeping Requirements

D.1.11 Reporting Requirements

Quarterly Report

SECTION A

SOURCE SUMMARY

This approval is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Management (OAM). The information describing the emission units contained in conditions A.1 through A.2 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this approval pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

The Permittee owns and operates a stationary source, chemical manufacturing operation that produces pharmaceutical preparation and agricultural chemicals.

Responsible Official: Kenny McCleary
Source Address: 1650 Lilly Road, Shadeland, Indiana 47909
Mailing Address: P.O. Box 685, Lafayette, Indiana 47902
Phone Number: 765-477-4006
SIC Code: 2834 & 2879
County Location: Tippecanoe
County Status: Attainment for all criteria pollutants
Source Status: Part 70 Permit Program
Existing Major Source, under PSD Rules;
Major Source, Section 112 of the Clean Air Act

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]

This stationary source is approved to construct and operate the following emission units and pollution control devices:

- (a) One (1) general process tank with a nominal capacity of 4,000 gallons, designated as Tank 24, located in an existing building designated as T100, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions, or by an existing caustic scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and caustic scrubbers, respectively.

The point source emissions from the process vessel may vent directly to RTO1 or RTO2, or it they may first vent to caustic scrubbers, process control condensers, vacuum sources, or through other process vessels before going to RTO1 or RTO2. If venting the process vessel to RTO1 or RTO2 would cause a safety concern, the process vessel may vent to an alternative pollution control device. Also, in the event that RTO1 or RTO2 is unavailable, Lilly may continue manufacturing operations in the process vessel using other existing pollution control equipment that complies with 326 IAC 8-5-3. The carbon monoxide emissions from the tank will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from the tank will be controlled by caustic scrubbers. The nitrogen oxides emissions from the tank will be voluntarily controlled by caustic scrubbers.

A.3 Part 70 Permit Applicability [326 IAC 2-7-2]

This stationary source has submitted a Part 70 permit application TV157-6879-00006 on October 10, 1996, pursuant to 326 IAC 2-7-2 (Applicability) because:

- (a) It is a major source, as defined in 326 IAC 2-7-1(22);
- (b) It is a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 - Applicability).

SECTION B GENERAL CONSTRUCTION CONDITIONS

B.1 Permit No Defense [IC 13]

This approval to construct does not relieve the Permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

B.2 Definitions [326 IAC 2-7-1]

Terms in this approval shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, any applicable definitions found in IC 13-11, 326 IAC 1-2 and 326 IAC 2-7 shall prevail.

B.3 Effective Date of the Permit [IC13-15-5-3]

Pursuant to IC 13-15-5-3, this approval becomes effective upon its issuance.

B.4 Revocation of Permits [326 IAC 2-1.1-9(5)][326 IAC 2-7-10.5(i)]

Pursuant to 326 IAC 2-1.1-9(5)(Revocation of Permits), the Commissioner may revoke this approval if construction is not commenced within eighteen (18) months after receipt of this approval or if construction is suspended for a continuous period of one (1) year or more.

B.5 Significant Source Modification [326 IAC 2-7-10.5(h)]

This document shall also become the approval to operate pursuant to 326 IAC 2-7-10.5(h) when, prior to start of operation, the following requirements are met:

- (a) The attached affidavit of construction shall be submitted to the Office of Air Management (OAM), Permit Administration & Development Section, verifying that the emission units were constructed as proposed in the application. The emissions units covered in the Significant Source Modification approval may begin operating on the date the affidavit of construction is postmarked or hand delivered to IDEM if constructed as proposed.
- (b) If actual construction of the emissions units differs from the construction proposed in the application, the source may not begin operation until the source modification has been revised pursuant to 326 IAC 2-7-11 or 326 IAC 2-7-12 and an Operation Permit Validation Letter is issued.
- (c) If construction is completed in phases; i.e., the entire construction is not done continuously, a separate affidavit must be submitted for each phase of construction. Any permit conditions associated with operation start up dates such as stack testing for New Source Performance Standards (NSPS) shall be applicable to each individual phase.
- (d) The Permittee shall receive an Operation Permit Validation Letter from the Chief of the Permit Administration & Development Section and attach it to this document.

However, in the event that the Title V application is being processed at the same time as this application, the following additional procedures shall be followed for obtaining the right to operate:

- (1) If the Title V draft permit has not gone on public notice, then the change/addition covered by the Significant Source Modification will be included in the Title V draft.
- (2) If the Title V permit has gone thru final EPA proposal and would be issued ahead of the Significant Source Modification, the Significant Source Modification will go thru a concurrent 45 day EPA review. Then the Significant Source Modification will be incorporated into the final Title V permit at the time of issuance.
- (3) If the Title V permit has not gone thru final EPA review and would be issued after the

Significant Source Modification is issued, then the Modification would be added to the proposed Title V permit, and the Title V permit will issued after EPA review.

SECTION C

GENERAL OPERATION CONDITIONS

C.1 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)] [326 IAC 2-7-6(1) and (6)] [326 IAC 1-6-3]

- (a) If required by specific condition(s) in Section D of this approval, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMP) within ninety (90) days after issuance of this approval, including the following information on each facility:
- (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;
 - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions;
 - (3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If due to circumstances beyond its control, the PMP cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

- (b) The Permittee shall implement the Preventive Maintenance Plans as necessary to ensure that failure to implement the Preventive Maintenance Plan does not cause or contribute to a violation of any limitation on emissions or potential to emit.
- (c) PMP's shall be submitted to IDEM, OAM, upon request and shall be subject to review and approval by IDEM, OAM. IDEM, OAM, may require the Permittee to revise its Preventive Maintenance Plan whenever lack of proper maintenance causes or contributes to any violation.

C.2 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]

- (a) The Permittee must comply with the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this approval.
- (b) Any application requesting an amendment or modification of this approval shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Management
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

Any such application should be certified by the "responsible official" as defined by 326 IAC 2-7-1(34) only if a certification is required by the terms of the applicable rule

- (c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

C.3 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following, unless otherwise stated in this approval:

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings) as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor in a six (6) hour period.

C.4 Operation of Equipment [326 IAC 2-7-6(6)]

Except as otherwise provided in this approval, all air pollution control equipment listed in this approval and used to comply with an applicable requirement shall be operated at all times that the emission unit vented to the control equipment is in operation.

Testing Requirements [326 IAC 2-7-6(1)]

C.5 Performance Testing [326 IAC 3-6][326 IAC 2-1.1-11]

- (a) Compliance testing on new emission units shall be conducted within 60 days after achieving maximum production rate, but no later than 180 days after initial start-up, if specified in Section D of this approval. All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this approval, utilizing any applicable procedures and analysis methods specified in 40 CFR 51, 40 CFR 60, 40 CFR 61, 40 CFR 63, 40 CFR 75, or other procedures approved by IDEM, OAM.

A test protocol, except as provided elsewhere in this approval, shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

no later than thirty-five (35) days prior to the intended test date. The Permittee shall submit a notice of the actual test date to the above address so that it is received at least two weeks prior to the test date.

- (b) All test reports must be received by IDEM, OAM within forty-five (45) days after the completion of the testing. An extension may be granted by the IDEM, OAM, if the source submits to IDEM, OAM, a reasonable written explanation within five (5) days prior to the end of the initial forty-five (45) day period.

The documentation submitted by the Permittee does not require certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Compliance Monitoring Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

C.6 Compliance Monitoring [326 IAC 2-1.1-11]

Compliance with applicable requirements shall be documented as required by this permit. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. All monitoring and record keeping requirements not already legally required shall be implemented when operation begins.

C.7 Pressure Transmitter Specifications

Whenever a condition in this permit requires the measurement of pressure drop across any part of the unit or its control device, the transmitter employed shall have a scale such that the expected normal reading shall be no less than twenty percent (20%) of full scale and be accurate within plus or minus two percent ($\pm 2\%$) of full scale reading.

Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

C.8 Compliance Monitoring Plan - Failure to Take Response Steps [326 IAC 2-7-5][326 IAC 2-7-6] [326 IAC 1-6]

- (a) The Permittee is required to implement a compliance monitoring plan to ensure that reasonable information is available to evaluate its continuous compliance with applicable requirements. This compliance monitoring plan is comprised of:
- (1) This condition;
 - (2) The Compliance Determination Requirements in Section D of this approval;
 - (3) The Compliance Monitoring Requirements in Section D of this approval;
 - (4) The Record Keeping and Reporting Requirements in Section C (Monitoring Data Availability, General Record Keeping Requirements, and General Reporting Requirements) and in Section D of this approval; and
 - (5) A Compliance Response Plan (CRP) for each compliance monitoring condition of this approval. CRP's shall be submitted to IDEM, OAM upon request and shall be subject to review and approval by IDEM, OAM. The CRP shall be prepared within ninety (90) days after issuance of this approval by the Permittee and maintained on site, and is comprised of :
 - (A) Response steps that will be implemented in the event that compliance related information indicates that a response step is needed pursuant to the requirements of Section D of this approval; and
 - (B) A time schedule for taking such response steps including a schedule for devising additional response steps for situations that may not have been predicted.
- (b) For each compliance monitoring condition of this approval, appropriate response steps shall be taken when indicated by the provisions of that compliance monitoring condition. Failure to perform the actions detailed in the compliance monitoring conditions or failure to take the response steps within the time prescribed in the Compliance Response Plan, shall constitute a violation of the approval unless taking the response steps set forth in the Compliance Response Plan would be unreasonable.

- (c) After investigating the reason for the excursion, the Permittee is excused from taking further response steps for any of the following reasons:
 - (1) The monitoring equipment malfunctioned, giving a false reading. This shall be an excuse from taking further response steps providing that prompt action was taken to correct the monitoring equipment.
 - (2) The Permittee has determined that the compliance monitoring parameters established in the approval conditions are technically inappropriate, has previously submitted a request for an administrative amendment to the approval, and such request has not been denied or;
 - (3) An automatic measurement was taken when the process was not operating; or
 - (4) The process has already returned to operating within "normal" parameters and no response steps are required.
- (d) Records shall be kept of all instances in which the compliance related information was not met and of all response steps taken. In the event of an emergency, the provisions of 326 IAC 2-7-16 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.

**C.9 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5]
[326 IAC 2-7-6]**

- (a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this approval exceed the level specified in any condition of this approval, the Permittee shall take appropriate corrective actions. The Permittee shall submit a description of these corrective actions to IDEM, OAM, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize emissions from the affected facility while the corrective actions are being implemented. IDEM, OAM shall notify the Permittee within thirty (30) days, if the corrective actions taken are deficient. The Permittee shall submit a description of additional corrective actions taken to IDEM, OAM within thirty (30) days of receipt of the notice of deficiency. IDEM, OAM reserves the authority to use enforcement activities to resolve noncompliant stack tests.
- (b) A retest to demonstrate compliance shall be performed within one hundred twenty (120) days of receipt of the original test results. Should the Permittee demonstrate to IDEM, OAM that retesting in one-hundred and twenty (120) days is not practicable, IDEM, OAM may extend the retesting deadline. Failure of the second test to demonstrate compliance with the appropriate approval conditions may be grounds for immediate revocation of the approval to operate the affected facility.

The documents submitted pursuant to this condition do not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

C.10 Monitoring Data Availability [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)]

- (a) With the exception of performance tests conducted in accordance with Section C- Performance Testing, all observations, sampling, maintenance procedures, and record keeping, required as a condition of this approval shall be performed at all times the equipment is operating at normal representative conditions.

- (b) As an alternative to the observations, sampling, maintenance procedures, and record keeping of subsection (a) above, when the equipment listed in Section D of this approval is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this approval.
- (c) If the equipment is operating but abnormal conditions prevail, additional observations and sampling should be taken with a record made of the nature of the abnormality.
- (d) If for reasons beyond its control, the operator fails to make required observations, sampling, maintenance procedures, or record keeping, reasons for this must be recorded.
- (e) At its discretion, IDEM may excuse such failure providing adequate justification is documented and such failures do not exceed five percent (5%) of the operating time in any quarter.
- (f) Temporary, unscheduled unavailability of staff qualified to perform the required observations, sampling, maintenance procedures, or record keeping shall be considered a valid reason for failure to perform the requirements stated in (a) above.

C.11 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]

- (a) Records of all required monitoring data and support information shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be kept at the source location for a minimum of three (3) years and available upon the request of an IDEM, OAM, representative. The records may be stored elsewhere for the remaining two (2) years as long as they are available within a reasonable time. If the Commissioner makes a written request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.
- (b) Records of required monitoring information shall include, where applicable:
 - (1) The date, place, and time of sampling or measurements;
 - (2) The dates analyses were performed;
 - (3) The company or entity performing the analyses;
 - (4) The analytic techniques or methods used;
 - (5) The results of such analyses; and
 - (6) The operating conditions existing at the time of sampling or measurement.
- (c) Support information shall include, where applicable:
 - (1) Copies of all reports required by this approval;
 - (2) All original strip chart recordings for continuous monitoring instrumentation;
 - (3) All calibration and maintenance records;

- (4) Records of preventive maintenance shall be sufficient to demonstrate that failure to implement the Preventive Maintenance Plan did not cause or contribute to a violation of any limitation on emissions or potential to emit. To be relied upon subsequent to any such violation, these records may include, but are not limited to: work orders, parts inventories, and operator's standard operating procedures. Records of response steps taken shall indicate whether the response steps were performed in accordance with the Compliance Response Plan required by Section C - Compliance Monitoring Plan - Failure to take Response Steps, of this approval, and whether a deviation from an approval condition was reported. All records shall briefly describe what maintenance and response steps were taken and indicate who performed the tasks.
- (d) All record keeping requirements not already legally required shall be implemented within ninety (90) days of approval issuance.

C.12 General Reporting Requirements [326 IAC 2-7-5(3)(C)]

- (a) The reports required by conditions in Section D of this approval shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015
- (b) Unless otherwise specified in this approval, any notice, report, or other submission required by this approval shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAM, on or before the date it is due.
- (c) Unless otherwise specified in this approval, any quarterly report shall be submitted within thirty (30) days of the end of the reporting period. The report does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).
- (d) The first report shall cover the period commencing on the date of submittal of the affidavit of construction and ending on the last day of the reporting period.

SECTION D.1

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]

- (a) One (1) general process tank with a nominal capacity of 4,000 gallons, designated as Tank 24, located in an existing building designated as T100, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions, or by an existing caustic scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and caustic scrubbers, respectively.

The point source emissions from the process vessel may vent directly to RTO1 or RTO2, or it they may first vent to caustic scrubbers, process control condensers, vacuum sources, or through other process vessels before going to RTO1 or RTO2. If venting the process vessel to RTO1 or RTO2 would cause a safety concern, the process vessel may vent to an alternative pollution control device. Also, in the event that RTO1 or RTO2 is unavailable, Lilly may continue manufacturing operations in the process vessel using other existing pollution control equipment that complies with 326 IAC 8-5-3. The carbon monoxide emissions from the tank will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from the tank will be controlled by caustic scrubbers. The nitrogen oxides emissions from the tank will be voluntarily controlled by caustic scrubbers.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.1.1 PSD Minor Limit [326 IAC 2-2] [40 CFR 52.21]

- (a) The source shall operated the caustic scrubber at all times when general process Tank 24 is emitting SO₂, and shall operate the regenerative thermal oxidizer (RTO) or condensers at all times when general process Tank 24 is emitting VOC.
- (b) When the SO₂ emissions from Tank 24 are controlled by the caustic scrubber, the pressure drop shall be maintained within the range of 1.0 to 3.0 inches of water or a range determined by a performance test to maintain at least 95% destruction of SO₂,
- (c) When the VOC emissions from the one (1) general process Tank 24 are controlled by
- (1) the existing Regenerative Thermal Oxidizer (RTO), the combustion chamber shall maintain a minimum operating temperature of 1600°F, or the temperature determined during the most recent stack tests, to maintain at least 90% destruction of volatile organic compounds, or
 - (2) the condensers shall maintain a maximum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds.

These conditions are necessary to make Prevention of Significant Deterioration (PSD) rules, 326 IAC 2-2 and 40 CFR 52.21, not applicable to this modification.

D.1.2 Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing [326 IAC 8-5-3]

- (a) Pursuant to 326 IAC 8-5-3 the outlet gas temperature shall not exceed the following when using condensers to control the VOC emissions from Tank 24:
- (1) minus twenty-five degrees Celsius (-25EC) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals (five and eight-tenths (5.8) pounds per square inch);

- (2) minus fifteen degrees Celsius (-15EC) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals (two and nine-tenths (2.9) pounds per square inch);
 - (3) zero degrees Celsius (0EC) when condensing VOC of vapor pressure greater than ten (10) kiloPascals (one and five-tenths (1.5) pounds per square inch);
 - (4) ten degrees Celsius (10EC) when condensing VOC of vapor pressure greater than seven (7) kiloPascals (one (1) pound per square inch); or
 - (5) twenty-five degrees Celsius (25EC) when condensing VOC of vapor pressure greater than three and five-tenths (3.5) kilo Pascals (five-tenths (0.5) pound per square inch).
 - (6) The vapor pressures listed above shall be measured at twenty degrees Celsius (20EC).
 - (7) If the equivalent control identified as RTO1 or RTO2 is used, the VOC emissions must be reduced by at least as much as they would be by using a surface condenser which meets the requirements of conditions (1) through (6) as applicable.
- (b) VOC emissions from tank 24 shall be controlled by the Regenerative Thermal Oxidizer system identified as RTO1 or RTO2 and shall be reduced:
- (1) by at least ninety percent (90%).
- (c) Pursuant to 326 IAC 8-5-3(b)(5), the Permittee shall install covers on all in process tanks that contain volatile organic compound. These covers shall be kept closed, unless production sampling, maintenance, or inspection procedures require operator access.
- (d) Pursuant to 326 IAC 8-5-3(b)(6), the Permittee shall repair all visible leaks from which a liquid, containing VOC, can be observed running or dripping. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

D.1.3 Leak Detection and Repair Requirements [326 IAC 20] [40 CFR Part 63, Subparts H & I]

That the owner or operator shall implement the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management, to reduce fugitive methylene chloride or carbon tetrachloride emissions from processes that use methylene chloride or carbon tetrachloride.

D.1.4 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for this facility and any control devices.

Compliance Determination Requirements

D.1.5 Testing Requirements [326 IAC 2-7-6(1),(6)][326 IAC 2-1.1-11]

The Permittee is not required to test this facility by this permit. The testing required for this facility will be deferred and shall follow the schedule in the Title V Permit, to determine compliance with 326 IAC 8-5-3. However, IDEM may require compliance testing when necessary to determine if the facility is in compliance. If testing is required by IDEM, compliance with the VOC and SO₂ limits specified in Conditions D.1.1 and D.1.2 shall be determined by a performance test conducted in accordance with Section C - Performance Testing.

D.1.6 VOC Emissions

Compliance with Condition D.1.1 and D.1.2 shall be demonstrated within 30 days of the end of each month based on the Tank 24 control device operational parameters for the most recent month.

Compliance Monitoring Requirements [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]

D.1.7 Parametric Monitoring

- (a) The Permittee shall monitor the total static pressure drop across the scrubber used in conjunction with Tank 24, at least once weekly when Tank 24 is emitting SO₂. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the scrubber shall be maintained at less than 1 inch of water per foot of packing. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.
- (b) The Permittee shall record the operating temperature of the Regenerative Thermal Oxidizers used in conjunction with Tank 24, at least once weekly when Tank 24 is emitting VOC. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the Regenerative Thermal Oxidizers shall be maintained at an operating temperature of at least 1,600 °F or a temperature determined during the most recent stack test to maintain at least 90% destruction of volatile organic compounds. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.

The instrument used for determining the pressure shall comply with Section C - Pressure Gauge Specifications, of this permit, shall be subject to approval by IDEM, OAM, and shall be calibrated at least once every six (6) months.

D.1.8 40 CFR Part 63, Subpart H and I (National Emissions Standard for Hazardous Air Pollutants)

That the owner or operator shall implement the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management, to reduce fugitive methylene chloride or carbon tetrachloride emissions from processes that use methylene chloride or carbon tetrachloride. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.

D.1.9 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production)

The General Tank 24 is subject to the National Emissions Standard for Hazardous Air Pollutants 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production). This process tank shall be in compliance with this NESHAP by the compliance date.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.1.10 Record Keeping Requirements

- (a) An owner or operator of the facility covered by this permit, when using the methylene chloride or carbon tetrachloride, shall comply with the record keeping requirements provided in the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management. The LDAR Program will fulfill the requirements of National Emissions Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H as required by the National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes subject to the Negotiate Regulation for Equipment Leaks, 40 CFR Part 63, Subpart I.
- (b) To document compliance with Conditions D.1.1, D.1.2 and D.1.8, the Permittee shall maintain the following:

- (1) Weekly records of the operating temperature during normal operation when venting to the atmosphere as pertains to the Recuperative Thermal Oxidizers.
 - (2) Daily records of the inlet and outlet differential static pressure during normal operation when venting to the atmosphere as pertains to the scrubber.
 - (3) Documentation of all response steps implemented, per event .
 - (4) Operation and preventive maintenance logs, including work purchases orders, shall be maintained.
 - (5) Quality Assurance/Quality Control (QA/QC) procedures.
 - (6) Operator standard operating procedures (SOP).
 - (7) Manufacturer's specifications or its equivalent.
 - (8) Equipment "troubleshooting" contingency plan.
 - (9) Documentation of the dates vents are redirected.
- (c) To document compliance with Conditions D.1.1 and D.1.7, the Permittee shall maintain the following:
- (1) records of the time during which the caustic scrubber, RTO or condenser serving Tank 24 were not operated;
 - (2) records of the reason that the caustic scrubber, RTO or condenser serving Tank 24 were not operated.
- (d) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

D.1.11 Reporting Requirements

- (a) A quarterly summary of the information to document compliance with Condition D.1.1 shall be submitted to the address listed in Section C - General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the quarter being reported.
- (b) Each owner or operator of a source shall submit the reports as required per the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management. The LDAR Program will fulfill the requirements of National Emissions Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H as required by the National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes subject to the Negotiate Regulation for Equipment Leaks, 40 CFR Part 63, Subpart I.

**INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR MANAGEMENT
COMPLIANCE DATA SECTION**

Part 70 Source Modification Quarterly Report

Source Name: Eli Lilly and Company, Tippecanoe Laboratories
Source Address: 1650 Lilly Road, Shadeland, Indiana 47909
Mailing Address: P.O. Box 685, Lafayette, Indiana 47902
Source Modification No.: SSM157-11031-00006
Facility: One (1) general process tank, designated as tank 24
Parameter: SO₂ and VOC emissions
Limit: (a) When the SO₂ emissions from Tank 24 are controlled by the caustic scrubber, the pressure drop shall be maintained within the range of 1.0 to 3.0 inches of water or a range determined by a performance test to maintain at least 95% destruction of SO₂,
(b) When the VOC emissions from the one (1) general process Tank 24 are controlled by:
(1) the existing Regenerative Thermal Oxidizer (RTO), the combustion chamber shall maintain a minimum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds, or
(2) the condensers shall maintain a maximum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds.

YEAR: _____

Month	SO ₂ Control Efficiency	VOC Control Efficiency
Month 1		
Month 2		
Month 3		

9 No deviation occurred in this quarter.

9 Deviation/s occurred in this quarter.
Deviation has been reported on: _____

Submitted by: _____
Title / Position: _____
Signature: _____
Date: _____
Phone: _____

Indiana Department of Environmental Management Office of Air Management

Addendum to the Technical Support Document (TSD) for a Part 70 Significant Source Modification

Source Name:	Eli Lilly and Company, Tippecanoe Laboratories
Source Location:	1650 Lilly Road, Shadeland, Indiana 47905
County:	Tippecanoe
SIC Code:	2834 & 2879
Operation Permit No.:	T157-6879-00006
Operation Permit Application Date:	October 10, 1996
Source Modification No.:	157-11031-00006
Permit Reviewer:	Phillip Ritz/EVP

On August 21, 1999, the Office of Air Management (OAM) had a notice published in the Journal & Courier, Lafayette, Indiana, stating that Eli Lilly and Company had applied for a Part 70 Significant Source Modification to construct and operate the addition of one (1) general process tank with a maximum capacity of 4,000 gallons, designated as Tank 24, to their existing stationary source, a chemical manufacturing operation that produces pharmaceutical preparations and agricultural chemicals. The notice also stated that OAM proposed to issue a Part 70 Significant Source Modification for this installation and provided information on how the public could review the proposed Part 70 Significant Source Modification and other documentation. Finally, the notice informed interested parties that there was a period of thirty (30) days to provide comments on whether or not this Part 70 Significant Source Modification should be issued as proposed.

On October 22, 1999, Stephani Moeller submitted comments on behalf of Eli Lilly and Company on the proposed Part 70 Significant Source Modification. The summary of the comments and corresponding responses is as follows:

Comment 1:

Please note that Comments 1 – 10 address the issue of the misnamed control device (~~Recuperative~~ **Regenerative** Thermal Oxidizer). Beginning with Comment 11, the remaining comments are organized in the order of the SSM conditions they address (i.e., Section A, B, C...).

Condition A.2 Emission Units and Pollution Control Equipment Summary of the draft Significant Source Modification should be revised to read as follows:

- (a) One (1) general process tank....controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO)...

Comment 2:

Section D.1, Facility Operation Conditions description paragraph, of the draft Significant Source Modification should be revised to read as follows:

- (a) One (1) general process tank....controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO)...

Comment 3:

Condition D.1.1, Operation of Equipment, of the draft Significant Source Modification should be revised to read as follows:

- (a) The source shall operate the caustic scrubber and ~~recuperative~~ **regenerative** thermal oxidizer...
- (c)(1) the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer...

Comment 4:

Condition D.1.8, Parametric Monitoring, of the draft Significant Source Modification should be revised to read as follows:

- (b) The Permittee shall record the operating temperature of the ~~Recuperative~~ **Regenerative** Thermal...
- ...Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the ~~Recuperative~~ **Regenerative** Thermal...

Comment 5:

Condition D.1.11, Record Keeping Requirements, of the draft Significant Source Modification should be revised to read as follows:

- (c)(1) ~~Daily~~**Weekly** records of the operating temperature during normal operation when venting to the atmosphere as pertains to the ~~Recuperative~~ **Regenerative** Thermal Oxidizers.

Comment 6:

Part 70 Source Modification Quarterly Report, Limit (b)(1) of the draft Significant Source Modification should be revised to read as follows:

the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO), the combustion chamber...

Comment 7:

The following paragraph in the "Source Background and Description" of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

- (a) One (1) general process tank with a maximum capacity of 4,000 gallons, designated as tank 24, located in an existing building designated as T100, and controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO) or...

Comment 8:

Section "State Rule Applicability – Individual Facilities, 326 IAC 2-2 (Prevention of Significant Deterioration)" (a) & (c)(1) of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

- (a) The source shall operate the caustic scrubber and ~~recuperative~~ **regenerative** thermal oxidizer (RTO) or...
- (c)(1) the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO), the combustion...

Comment 9:

Section "Compliance Requirements" of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

- (a)(2) The Permittee shall record the operating temperature of the ~~Recuperative~~ **Regenerative** Thermal Oxidizers (RTO) used in conjunction...the pressure drop across the ~~Recuperative~~ **Regenerative** Thermal Oxidizers shall be maintained...
- (a)(4) ...These monitoring conditions are necessary because the caustic scrubber and ~~Recuperative~~ **Regenerative** Thermal Oxidizers for the one...

Comment 10:

If there are any other instances where the term "Recuperative Thermal Oxidizer(s)" is used, they also need to be revised to read "~~Recuperative~~ **Regenerative** Thermal Oxidizer(s)."

Responses 1 through 10:

The term Recuperative Thermal Oxidizer has been replaced with Regenerative Thermal Oxidizer to correct the typographical error. The changes to the permit are as follows:

- (1) Condition A.2, Emission Units and Pollution Control Equipment Summary, of the draft Significant Source Modification has been revised to read as follows:
 - (a) One (1) general process tank...controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO)...
- (2) Section D.1, Facility Operation Conditions description paragraph, of the Part 70 Significant Source Modification has been revised to read as follows:
 - (a) One (1) general process tank...controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO)...
- (3) Condition D.1.1, Operation of Equipment, of the Part 70 Significant Source Modification has been revised to read as follows:
 - (a) The source shall operate the caustic scrubber and ~~recuperative~~ **regenerative** thermal oxidizer...
 - (c)(1) the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer...
- (4) Condition D.1.8, Parametric Monitoring, of the Part 70 Significant Source Modification has been revised to read as follows:
 - (b) The Permittee shall record the operating temperature of the ~~Recuperative~~ **Regenerative** Thermal...

...Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the ~~Recuperative~~ **Regenerative** Thermal...
- (5) Condition D.1.11, Record Keeping Requirements, of the Part 70 Significant Source Modification has been revised to read as follows:
 - (c)(1) Daily records of the operating temperature during normal operation when venting to the atmosphere as pertains to the ~~Recuperative~~ **Regenerative** Thermal Oxidizers.

- (6) Part 70 Source Modification Quarterly Report, Limit (b)(1) of the Part 70 Significant Source Modification has been revised to read as follows:

the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO), the combustion chamber shall maintain a minimum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds, or

The following revisions have been made to the Technical Support Document under Compliance Requirements (**bolded** language has been added, the language with a line through it has been deleted). The OAM prefers that the Technical Support Document reflect the permit that was on public notice. Changes to the permit or technical support material that occur after the public notice are documented in this Addendum to the Technical Support Document. This accomplishes the desired result of ensuring that these types of concerns are documented and part of the record regarding this permit decision.

- (7) The following paragraph in the "Source Background and Description" of the Technical Support Document (TSD) of the Part 70 Significant Source Modification has been revised to read as follows:

- (a) One (1) general process tank with a maximum capacity of 4,000 gallons, designated as tank 24, located in an existing building designated as T100, and controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO) or...

- (8) Section "State Rule Applicability – Individual Facilities, 326 IAC 2-2 (Prevention of Significant Deterioration)" (a) & (c)(1) of the Technical Support Document (TSD) of the Part 70 Significant Source Modification has been revised to read as follows:

- (a) The source shall operate the caustic scrubber and ~~recuperative~~ **regenerative** thermal oxidizer (RTO) or...
(c)(1) the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO), the combustion...

- (9) Section "Compliance Requirements" of the Technical Support Document (TSD) of the Part 70 Significant Source Modification has been revised to read as follows:

- (a)(2) The Permittee shall record the operating temperature of the ~~Recuperative~~ **Regenerative** Thermal Oxidizers (RTO) used in conjunction...the pressure drop across the ~~Recuperative~~ **Regenerative** Thermal Oxidizers shall be maintained...
(a)(4) ...These monitoring conditions are necessary because the caustic scrubber and ~~Recuperative~~ **Regenerative** Thermal Oxidizers for the one...

Comment 11:

The first paragraph in Section A of the draft Significant Source Modification should be revised to read as follows:

...The information describing the emission units contained in Conditions A.1 through A.2 **and in the Facility Description D.1** is descriptive information and does not...

Response 11:

Facility descriptions are not federally enforceable, and a Facility Description Box is not a permit condition and is not federally enforceable. It is stated in Section A of every permit that facility descriptions in A.1 through A.3 are not federally enforceable. In order to avoid confusion on this issue, additional language will be added into the Facility Description Box contained in Section D to further clarify that facility descriptions are not federally enforceable.

Facility Description [326 IAC 2-7-5(15)]:

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Comment 12:

Condition A.1 General Information of the draft Significant Source Modification should be revised to read as follows:

Responsible Official: ~~Stephani Moeller~~ **Kenny McCleary**
Source Address: 1650 Lilly Road, Shadeland, Indiana ~~47905~~ **47909**
Phone Number: 765-477-~~4867~~ **4006**

(Note: Correction of responsible official & update of recent zip code reassignment.)

Response 12:

In Section A.1, and in the certification and report forms, the responsible official, zip code, and phone number have been changed as follows:

Responsible Official: ~~Stephani Moeller~~ **Kenny McCleary**
Source Address: 1650 Lilly Road, Shadeland, Indiana ~~47905~~ **47909**
Phone Number: 765-477-~~4867~~ **4006**

Comment 13:

Condition A.2 Emission Units and Pollution Control Equipment Summary of the draft Significant Source Modification should be revised to read as follows:

- (a) One (1) general process tank with a ~~maximum~~ **nominal** capacity of 4,000 gallons, designated as ~~tank~~ **Tank 24**, located in an existing building designated as T100, and **capable of being** controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO) or condenser for VOC emissions, ~~and or by~~ **and or by** an existing caustic scrubber...

The point source emissions from the process vessel may vent directly to RTO1 or RTO2, or if **they** may first vent to caustic scrubbers, process control condensers, vacuum sources, or through other process ~~vessel~~ **vessels** before going to... Also, in the event that RTO1 or RTO2 is unavailable, Lilly ~~would~~ **may** continue manufacturing operations in the process vessel using other existing pollution control equipment that complies with 326 IAC 8-5-3 ~~and 326 IAC 2-2~~. The carbon monoxide emissions from the ~~replacement~~ tank will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from the ~~replacement~~ tank will be ~~voluntarily~~ controlled by caustic scrubbers. The nitrogen oxides emissions from the ~~replacement~~ tank will be voluntarily controlled by caustic scrubbers.

(Note: 326 IAC 2-2 does not apply to Tank 24 – see Condition D.1.1. This is a new tank installation, not a tank replacement. Also, the conditions of this permit will require that sulfur dioxide emissions are controlled by the scrubber and thus will not be “voluntarily” controlled.)

Response 13:

The source is already a major PSD source. This modification to the source is determined to be a minor PSD modification. This is because the source has accepted the use of controls to reduce VOC and SO₂ emissions. The use of these controls will prevent 326 IAC 2-2 and 40 CFR 52.21 from being applicable.

The emissions of SO₂ emissions are not voluntarily controlled and have been clarified to remove the words “voluntary”. Tank 24 is not a replacement tank, and the word “replacement” has been removed from the unit description. The changes to the permit have been made as follows:

**A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)]
[326 IAC 2-7-5(15)]**

This stationary source is approved to construct and operate the following emission units and pollution control devices:

- (a) One (1) general process tank with a ~~maximum~~ **nominal** capacity of 4,000 gallons, designated as ~~tank~~ **Tank 24**, located in an existing building designated as T100, and **capable of being** controlled by the existing ~~Regenerative~~ **Regenerative** Thermal Oxidizer (RTO) or condenser for VOC emissions, ~~and or by~~ an existing caustic scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and caustic scrubbers, respectively.

The point source emissions from the process vessel may vent directly to RTO1 or RTO2, or it ~~they~~ may first vent to caustic scrubbers, process control condensers, vacuum sources, or through other process ~~vessel~~ **vessels** before going to RTO1 or RTO2. If venting the process vessel to RTO1 or RTO2 would cause a safety concern, the process vessel may vent to an alternative pollution control device. Also, in the event that RTO1 or RTO2 is unavailable, Lilly ~~would~~ **may** continue manufacturing operations in the process vessel using other existing pollution control equipment that complies with 326 IAC 8-5-3 ~~and 326 IAC 2-2~~. The carbon monoxide emissions from the ~~replacement~~ tank will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from the ~~replacement~~ tank will be ~~voluntarily~~ controlled by caustic scrubbers. The nitrogen oxides emissions from the ~~replacement~~ tank will be voluntarily controlled by caustic scrubbers.

Comment 14:

Condition B.5 Significant Source Modification [326 IAC 2-7-10.5(h)] of the draft Significant Source Modification should be revised to read as follows:

~~However, in the event that...~~

- ~~_____ (1)~~
- ~~_____ (2)~~
- ~~_____ (3)~~

The requirements of this source modification will be included in Tippecanoe Laboratories draft Title V permit.

Response 14:

The source is already a major PSD source. This modification to the source is determined to be a minor PSD modification. This is because the source has accepted the use of controls to reduce VOC and SO₂ emissions. The use of these controls will prevent 326 IAC 2-2 and 40 CFR 52.21 from being applicable.

Comment 15:

Condition C.1 Certification [326 IAC 2-7-4(f)] [326 IAC 2-7-5(3)(C)] (and related references throughout the SSM) of the draft Significant Source Modification should be deleted due to the following reason:

The Significant Source Modification Approval is being issued pursuant to 326 IAC 2-7-10.5. Neither 326 IAC 2-7-4(f) or 326 IAC 2-7-5(3)(C) are applicable. There are no "Responsible Official" certification requirements for source modifications at sources without Title V permits.

Response 15:

The source is not subject to 326 IAC 2-7-4(f) or 326 IAC 2-7-5(3)(C), therefore Condition C.1 Certification [326 IAC 2-7-4(f)] [326 IAC 2-7-5(3)(C)] has been deleted from the permit, and the remaining conditions have been renumbered.

Comment 16:

Condition C.2 Preventive Maintenance Plan [326 IAC 2-7-5(1), (3) and (13)] [326 IAC 2-7-6(1) and (6)] [326 IAC 1-6-3] of the draft Significant Source Modification should be revised to read as follows:

1. If required by specific condition(s) in Section D of this approval, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMP) within ninety (90) days after issuance of this approval, including...
2. The Permittee shall implement the Preventive Maintenance Plans as necessary to ensure that failure to implement the Preventive Maintenance Plan does not cause or contribute to a violation of any limitation on emissions or potential to emit.
3. PMP's shall be submitted to IDEM, OAM, upon request and shall be subject to review and approval by IDEM, OAM. ~~IDEM, OAM, may require the Permittee to revise its Preventive Maintenance Plan whenever lack of proper maintenance causes or contributes to any violation.~~

PMP submitted by the Permittee does not require certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(Note: The additional text would not be necessary if all references to responsible official are deleted from this SSM)

Response 16:

OAM has not stated that the submittal requires a responsible official certification. The Preventive Maintenance Plan requirement must be included in every applicable Title V permit pursuant to 326 IAC 2-7-5(13). This rule refers back to the Preventive Maintenance Plan requirement as described in 326 IAC 1-6-3.

The commissioner may require changes in the maintenance plan to reduce excessive malfunctions in any control device or combustion or process equipment under 326 IAC 1-6-5. There has been no change to the permit as a result of this comment.

Comment 17:

Condition C.3 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12] of the draft Significant Source Modification should be revised to read as follows:

C.3 Permit Amendment or Modification **[326 IAC 2-7-10.5]** [326 IAC 2-7-11] [326 IAC 2-7-12]

- (a) The Permittee must comply with the requirements of **326 IAC 2-7-10.5**, 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this approval.

Response 17:

The addition of the source modification rule citation (326 IAC 2-7-10.5) to Condition C.3 Permit Amendment or Modification is unnecessary. As the condition states, the Permittee must comply with the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this approval. 326 IAC 2-7-10.5 refers to the modification of the source to construct emission units, modify existing emission units, or otherwise modify the source. Operation of the changes/modifications listed in 326 IAC 2-7-10.5 cannot commence until approval under 326 IAC 2-7-11 or 326 IAC 2-7-12, which incorporates the changes/modifications into the Part 70 operating permit, has been issued. There have been no changes to this permit as a result of this comment.

Comment 18:

Condition C.6 Stack Height [326 IAC 1-7] of the draft Significant Source Modification should be revised to read as follows:

The Permittee shall comply with the applicable provisions of 326 IAC 1-7 (Stack Height Provisions), for all exhaust stacks through which a potential (before controls) of twenty-five (25) tons per year or more of particulate matter or sulfur dioxide is emitted by using ~~ambient air quality modeling pursuant to 326 IAC 1-7-4~~ **good engineering practices (GEP) pursuant to 326 IAC 1-7-3.**

Response 18:

Pursuant to 326 IAC 1-7-5(a), the stack from this emission unit has less than 25 tons per year of potential emissions of PM and SO₂, and is therefore exempt from the requirements specified in 326 IAC 1-7. Condition C.6 has been removed from the permit as follows, and the remaining permit conditions have been renumbered:

~~C.6 — Stack Height [326 IAC 1-7]~~

~~The Permittee shall comply with the applicable provisions of 326 IAC 1-7 (Stack Height Provisions), for all exhaust stacks through which a potential (before controls) of twenty-five (25) tons per year or more of particulate matter or sulfur dioxide is emitted by using ambient air quality modeling pursuant to 326 IAC 1-7-4.~~

Comment 19:

Subsection Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)] of the draft Significant Source Modification should correct a typographical error as follows:

Compliance Monitoring Requirements [326 IAC 2-7-5~~(1)~~**(3)**] [326 IAC 2-7-6(1)]

Comment 20:

Condition C.8 Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)] of the draft Significant Source Modification should be revised to read as follows:

Compliance with applicable requirements shall be documented as required by this approval. All monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of approval issuance submittal of the affidavit of construction. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment...

Responses 19 and 20:

This permit contains new construction, and monitoring and record keeping requirements not already legally required shall be implemented upon approval issuance. The following changes have been made Condition C8 (now C.6) of the permit to clarify that all monitoring and record keeping requirements not already legally required shall be implemented when operation begins:

~~Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]~~

~~Compliance with applicable requirements shall be documented as required by this approval. All monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of submittal of the affidavit of construction. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. If due to circumstances beyond its control, that equipment cannot be installed and operated within ninety (90) days, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:~~

~~Indiana Department of Environmental Management
Compliance Branch, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015~~

~~in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.~~

~~The notification which shall be submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).~~

Compliance Monitoring [326 IAC 2-1.1-11]

Compliance with applicable requirements shall be documented as required by this permit. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. All monitoring and record keeping requirements not already legally required shall be implemented when operation begins.

Comment 21:

Condition C.10 Pressure Gauge Specifications should be deleted due to the following reason:

In order to monitor a pressure drop across a scrubber, a pressure transmitter, not a pressure gauge, would be used. These specifications are therefore not applicable.

Response 21:

This condition requires the Permittee to operate their control equipment or the process unit, with no less than 20 percent of the full scale and accuracy within plus or minus two percent of full scale reading. The pressure transmitter provides information to an operator that the process or control device is working properly within the vendor's specifications. Condition C.10 (now C.7) (Pressure Transmitter Specifications) is required by OAM to ensure that the operational parameters that are set in the permit are in fact being met by the source. Without requiring a certain degree of accuracy in the equipment, the operating parameters OAM sets will not have much meaning. The language used in Condition C.10 of the permit has been changed to require

Pressure Transmitter Specifications:

C.407 Pressure Gauge Transmitter Specifications

Whenever a condition in this permit requires the measurement of pressure drop across any part of the unit or its control device, the **gauge transmitter** employed shall have a scale such that the expected normal reading shall be no less than twenty percent (20%) of full scale and be accurate within plus or minus two percent ($\pm 2\%$) of full scale reading.

Comment 22:

Condition C.11 Compliance Monitoring Plan – Failure to Take Response Steps of the draft Significant Source Modification should be deleted due to the following reason:

These provisions create a "Compliance Response Plan" and requirements to implement such a plan. These provisions create a potential enforcement liability for a Permittee, if the Permittee fails to implement the Compliance Response Plan. There is no regulatory authority in IDEM's permitting rules for either establishing such requirements or potential violations. Therefore, Lilly objects to these provisions being included in any permit issued to the company.

Response 22:

IDEM has worked with members of the Clean Air Act Advisory Council's Permit Committee, Indiana Manufacturing Association, Indiana Chamber of Commerce and individual applicants regarding the Preventive Maintenance Plan, the Compliance Monitoring Plan and the Compliance Response Plan. IDEM has clarified the preventive maintenance requirements by working with sources on draft language over the past two years. The plans are fully supported by rules promulgated by the Air Pollution Control Board. The plans are the mechanism each permittee will use to verify continuous compliance with its permit and the applicable rules and will form the basis for each permittee's Annual Compliance Certification. Each permittee's ability to verify continuous compliance with its air pollution control requirements is a central goal of the Title V and FESOP permit programs.

The regulatory authority for and the essential elements of a compliance monitoring plan were clarified in IDEM's Compliance Monitoring Guidance, in May 1996. IDEM originally placed all the preventive maintenance requirements in the permit section titled "Preventive Maintenance Plan." Under that section the permittee's Preventive Maintenance Plan (PMP) had to set out requirements for the inspection and maintenance of equipment both on a routine basis and in response to monitoring. Routine maintenance was a set schedule of inspections and maintenance of the equipment. The second was inspection and maintenance in response to monitoring that showed that the equipment was not operating in its normal range. This monitoring would indicate that maintenance was required to prevent the exceedance of an emission limit or other permit requirement. The maintenance plan was to set out the "corrective actions" that the permittee would take in the event an inspection indicated an "out of specification situation," and also set out the time frame for taking the corrective action. In addition, the PMP had to include a schedule for devising additional corrective actions for out of compliance situations that the source had not predicted in the PMP. All these plans, actions and schedules were part of the Preventive Maintenance Plan, with the purpose of maintaining the permittee's equipment so that an exceedance of an emission limit or violation of other permit requirements could be prevented.

After issuing the first draft Title V permits on public notice in July of 1997, IDEM received comments from members of the regulated community regarding many of the draft permit terms, including the PMP requirements. One suggestion was that the corrective action and related schedule requirements be removed from the PMP requirement and placed into some other requirement in the permit. This suggestion was based, in some part, on the desire that a

permittee's maintenance staff handle the routine maintenance of the equipment, and a permittee's environmental compliance and engineering staff handle the compliance monitoring and steps taken in reaction to an indication that the facility required maintenance to prevent an environmental problem.

IDEM carefully considered this suggestion and agreed to separate the "corrective actions" and related schedule requirements from the PMP. These requirements were placed into a separate requirement, which IDEM named the Compliance Response Plan (CRP). In response to another comment, IDEM changed the name of the "corrective actions" to "response steps." That is how the present CRP requirements became separated from the PMP requirement, and acquired their distinctive nomenclature.

Other comments sought clarification on whether the failure to follow the PMP was violation of the permit. The concern was that a permittee's PMP might call for the permittee to have, for example, three "widget" replacement parts in inventory. If one widget was taken from inventory for use in maintenance, then the permittee might be in violation of the PMP, since there were no longer three widgets in inventory, as required by the PMP. Comments also expressed a view that if a maintenance employee was unexpectedly delayed in making the inspection under the PMP's schedule, for example by the employee's sudden illness, another permit violation could occur, even though the equipment was still functioning properly.

IDEM considered the comments and revised the PMP requirement so that if the permittee fails to follow its PMP, a permit violation will occur only if the lack of proper maintenance causes or contributes to a violation of any limitation on emissions or potential to emit. This was also the second basis for separating the compliance maintenance response steps from the PMP and placing them in the Compliance Response Plan (CRP). Unlike the PMP, the permittee must conduct the required monitoring and take any response steps as set out in the CRP (unless otherwise excused) or a permit violation will occur.

The Compliance Monitoring Plan is made up of the PMP, the CRP, the compliance monitoring and compliance determination requirements in section D of the permit, and the record keeping and reporting requirements in sections C and D. IDEM decided to list all these requirements under this new name, the Compliance Monitoring Plan (CMP), to distinguish them from the PMP requirements. The section D provisions set out which facilities must comply with the CMP requirement. The authority for the CMP provisions is found at 326 IAC 2-7-5(1), 2-7-5(3), 2-7-5(13), 2-7-6(1), 1-6-3 and 1-6-5.

Most permittees already have a plan for conducting preventive maintenance for the emission units and control devices. It is simply a good business practice to have identified the specific personnel whose job duties include inspecting, maintaining and repairing the emission control devices. The emission unit equipment and the emission control equipment may be covered by a written recommendation from the manufacturer set out schedules for the regular inspection and maintenance of the equipment. The permittee will usually have adopted an inspection and maintenance schedule that works for its particular equipment and process in order to keep equipment downtime to a minimum and achieve environmental compliance. The manufacturer may also have indicated, or the permittee may know from experience, what replacement parts should be kept on hand. The permittee may already keep sufficient spare parts on hand so that if a replacement is needed, it can be quickly installed, without a delay in the permittee's business activities and without an environmental violation. For the most part, the PMP can be created by combining present business practices and equipment manufacturer guidance into one document, the Preventive Maintenance Plan (PMP).

The permittee has 90 days to prepare, maintain and implement the PMP. IDEM is not going to draft the PMP. Permittees know their processes and equipment extremely well and are in the best position to draft the PMP. IDEM's air inspectors and permit staff will be available to assist the permittee with any questions about the PMP. IDEM may request a copy of the PMP to review and approve.

The Preventive Maintenance Plan requirement must be included in every applicable Title V permit pursuant to 326 IAC 2-7-5(13) and for each FESOP permit pursuant to 326 IAC 2-8-4(9). Both of those rules refer back to the Preventive Maintenance Plan requirement as described in 326 IAC 1-6-3. This Preventive Maintenance Plan rule sets out the requirements for:

- (1) Identification of the individuals responsible for inspecting, maintaining and repairing the emission control equipment (326 IAC 1-6-3(a)(1)),
- (2) The description of the items or conditions in the facility that will be inspected and the inspection schedule for said items or conditions (326 IAC 1-6-3(a)(2)), and
- (3) The identification and quantification of the replacement parts for the facility which the permittee will maintain in inventory for quick replacement (326 IAC 1-6-3(a)(2)).

It is clear from the structure of the wording in 326 IAC 1-6-3 that the PMP requirement affects the entirety of the applicable facilities. Only 326 IAC 1-6-3(a)(1) is limited, in that it requires identification of the personnel in charge of only the emission control equipment, and not any other facility equipment. The commissioner may require changes in the maintenance plan to reduce excessive malfunctions in any control device or combustion or process equipment under 326 IAC 1-6-5.

The CRP requirement of response steps and schedule requirements are another example of documenting procedures most permittees already have developed in the course of good business practices and the prevention of environmental problems. Equipment will often arrive with the manufacturer's trouble shooting guide. It will specify the steps to take when the equipment is not functioning correctly. The steps may involve some initial checking of the system to locate the exact cause, and other steps to place the system back into proper working order. Using the trouble shooting guide and the permittee's own experience with the equipment, the steps are taken in order and as scheduled until the problem is fixed.

A permittee will likely already have a procedure to follow when an unforeseen problem situation occurs. The procedure may list the staff to contact in order to select a course of action, or other step, before the equipment problem creates an environmental violation or interrupts the permittee's business process.

The Compliance Monitoring Plan (CMP) is consistent with IDEM's Compliance Monitoring Guidance released in May of 1996. The guidance discusses corrective action plans setting out the steps to take when compliance monitoring shows an out of range reading (Guidance, page 13). Some of the terminology has changed, as a result of comments from regulated sources, but the requirements in the permit do not conflict with the guidance. There have been no changes to this permit as a result of this comment.

Comment 23:

Condition C.12 (Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5]) of the draft Significant Source Modification should be revised to read as follows:

~~A retest to demonstrate compliance...may extend the retesting deadline. Failure of the second test to demonstrate compliance with the appropriate approval conditions may be grounds for immediate revocation of the approval to operate the affected facility.~~

(Note: There is no regulatory authority in IDEM's permitting rules for such a provision)

Response 23:

OAM has authority under 326 IAC 2-1.1-9 to require this condition. 326 IAC 2-1.1-9 states that: any permit to construct or operate or any permit revision approval granted by the commissioner may be revoked for any of the following reasons:

- (1) Violation of any conditions of the permit or permit revision approval.
- (2) Failure to disclose all the relevant facts or misrepresentation in obtaining the permit or permit revision approval.
- (3) Changes in regulatory requirements that mandate either a temporary or permanent reduction of discharge of contaminants. However, the amendment of appropriate sections of a permit shall not require revocation of a permit.
- (4) Noncompliance with an order issued pursuant to 326 IAC 1-5 to reduce emissions during an air pollution episode.
- (5) For a permit authorizing construction, failure to commence construction of the source or emissions unit within eighteen (18) months from the date of the issuance of the permit, or if during the construction of the source or emissions unit, work is suspended for a continuous period of one (1) year or more.
- (6) Any other cause that establishes in the judgment of the commissioner the fact that continuance of the permit or permit revision approval is not consistent with the purposes of this article.

Therefore, the language stating that the "failure of the second test to demonstrate compliance with the appropriate approval conditions may be grounds for immediate revocation of the approval to operate the affected facility" shall not be removed from the permit. There have been no changes to the permit as a result of this comment.

Comment 24:

Condition C.13 Monitoring Data Availability [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)] of the draft Significant Source Modification should be revised to read as follows:

1. With the exception...performed at all times the equipment **listed in Section D.1** is operating at normal representative conditions **and emitting a pollutant for which this approval requires emission controls.**
2. As an alternative to...when the equipment listed in Section ~~D~~ **D.1** of this approval...
3. If the equipment **listed in Section D.1** is operating...

Response 24:

The term "normal representative condition" refers to when all observations, sampling, maintenance procedures, and record keeping, required as a condition of this permit shall be performed, and must represent those conditions. The wording already encompasses the emission of a pollutant which requires emission controls. Condition C.13 is not limited to facilities with controls, rather, it applies to any emitting facility. Condition C.13(a) requires that all usual observations, sampling, maintenance procedures and record keeping required as a condition of the permit shall be performed when the equipment is operating at normal representative conditions. It clarifies when the observations, sampling, maintenance procedures, and record keeping, required as a condition of this permit are to be performed. As stated on the cover page of the permit, the emission units described in Section A (Source Summary) of this approval are permitted to construct and operate subject to the conditions

contained within the permit. Therefore, this condition applies to all records required in Section D. The purpose of Section C is to state general conditions once, so that they do not have to be restated in every subsection of Section D. Unless a term in Section D states otherwise, the Section C general term applies. As there is only one Section D in this permit, mention of equipment or Section D relates solely to the equipment listed in Section D.1, and this condition has not been changed as a result of this comment.

Condition C - Monitoring Data Availability says: when the equipment listed in Section D of this permit is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this permit. There will be no changes to this condition in the final permit due to this comment.

Comment 25:

Condition C.14, General Record Keeping Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6], of the draft Significant Source Modification should be revised to read as follows:

- (a) Records of all required monitoring...These records shall be kept at the source location for a minimum of three (3) years and available **within a reasonable time period** upon request of an IDEM, OAM, representative. The records may be stored elsewhere for the remaining two (2) years as long as they are available **within thirty (30) days of a written request from the Commissioner.** ~~upon request. If the Commissioner makes a written request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.~~
- (b) Records of required monitoring information shall include, where ~~applicable~~ **specified in Section D:**
- (c) Support information shall include, where ~~applicable~~ **specified in Section D:**
- ~~(c)(4) Records of preventive maintenance shall be sufficient to demonstrate that...indicate who performed the tasks.~~

Response 25:

This condition is almost exactly the wording required by 326 IAC 2-7-5(3). 40 CFR 70.6(f) states that the permitting authority may expressly include in a Part 70 permit a provision stating that compliance with the conditions of the permit shall be deemed in compliance with any applicable requirements.

Condition C.14 (now C.11) requires that records necessary to document compliance be kept at the source for a period of three (3) years, and then may be stored elsewhere for the next two (2) years provided the records can be made available within thirty (30) days after written request. Because the most recent three years worth of records must be kept at the source, it is reasonable to assume that such records can be produced within a short time frame when OAM staff requests such data. In OAM's experience, practical requests for compliance related records can be made available within one hour. 326 IAC 2-7-6(2) states that the permittee shall allow access to records when the inspector arrives at the source.

OAM has ample authority for this condition. The OAM believes that citing "upon request" as stated in the rule is the preferable language, specifically during the first three years. Generally sources and the OAM can come to an agreement on the amount of time needed to produce records, especially if the request requires a substantial amount of information. The OAM agrees that the language can be changed as suggested for the remaining two years. Condition C.23(a) now reads (deleted language in ~~strikeout~~, add language in **bold**):

C.1411 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]

- (a) Records of all required monitoring data and support information shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be kept at the source location for a minimum of three (3) years and available upon the request of an IDEM, OAM, representative. The records may be stored elsewhere for the remaining two (2) years as long as they are available ~~upon request~~ **within a reasonable time**. If the Commissioner makes a written request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

Comment 26:

Condition C.15 General Reporting Requirements [326 IAC 2-7-5(3)(C)] of the draft Significant Source Modification should be revised to read as follows:

- (d) The first report shall cover the period commencing on the date of ~~issuance of this approval~~ **submittal of the affidavit of construction** and ending on the last day of the reporting period.

Response 26:

The Office of Air Management (OAM) agrees that Condition C.15 (now C.11), General Reporting Requirements, on Page 11 of 18 (now page 9 of 15) of the proposed permit, are operation conditions, and were revised to apply only after operation commences. The changes to the permit are as follows

- (d) The first report shall cover the period commencing on the date of ~~issuance of this approval~~ **submittal of the affidavit of construction** and ending on the last day of the reporting period.

Comment 27:

Section D.1, Facility Operation Conditions description paragraph of the draft Significant Source Modification, should be revised to read as follows:

One (1) general process tank with a maximum capacity of 4,000 gallons, designated as ~~tank~~ **Tank 24**, located in an existing building designated as T100, and **capable of being** controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO) or condenser for VOC emissions, ~~and~~ or by an existing caustic scrubber...

The point source emissions from the process vessel may vent directly to RTO1 or RTO2, or it they may first vent to caustic scrubbers, process control condensers, vacuum sources, or through other process ~~vessel~~ **vessels** before going to... Also, in the event that RTO1 or RTO2 is unavailable, Lilly ~~would~~ **may** continue manufacturing operations in the process vessel using other existing pollution control equipment that complies with 326 IAC 8-5-3 ~~and 326 IAC 2-2~~. The carbon monoxide emissions from the ~~replacement~~ tank will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from the ~~replacement~~ tank will be ~~voluntarily~~ controlled by caustic scrubbers. The nitrogen oxides emissions from the ~~replacement~~ tank will be voluntarily controlled by caustic scrubbers.

(326 IAC 2-2 does not apply to Tank 24 – see Condition D.1.1. This is a new tank installation, not a tank replacement. Also, the conditions of this permit will require that sulfur dioxide emissions are controlled by the scrubber and thus will not be “voluntarily” controlled.)

Response 27:

The source is already a major PSD source. This modification to the source is determined to be a minor PSD modification. This is because the source has accepted the use of controls to reduce VOC and SO₂ emissions. The use of these controls will prevent 326 IAC 2-2 and 40 CFR 52.21 from being applicable.

The emissions of SO₂ emissions are not voluntarily controlled and have been clarified to remove the words "voluntary". Tank 24 is not a replacement tank, and the word "replacement" has been removed from the unit description. The changes to the permit have been made as follows:

Facility Description [326 IAC 2-7-5(15)]

- (a) One (1) general process tank with a ~~maximum~~ **nominal** capacity of 4,000 gallons, designated as ~~tank~~ **Tank 24**, located in an existing building designated as T100, and **capable of being** controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO) or condenser for VOC emissions, ~~and or by~~ an existing caustic scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and caustic scrubbers, respectively.

The point source emissions from the process vessel may vent directly to RTO1 or RTO2, or if **they** may first vent to caustic scrubbers, process control condensers, vacuum sources, or through other process ~~vessel~~ **vessels** before going to RTO1 or RTO2. If venting the process vessel to RTO1 or RTO2 would cause a safety concern, the process vessel may vent to an alternative pollution control device. Also, in the event that RTO1 or RTO2 is unavailable, Lilly ~~would may~~ continue manufacturing operations in the process vessel using other existing pollution control equipment that complies with 326 IAC 8-5-3 ~~and 326 IAC 2-2~~. The carbon monoxide emissions from the ~~replacement~~ tank will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from the ~~replacement~~ tank will be ~~voluntarily~~ controlled by caustic scrubbers. The nitrogen oxides emissions from the ~~replacement~~ tank will be voluntarily controlled by caustic scrubbers.

Comment 28:

Condition D.1.1 PSD Minor Limit [326 IAC 2-2] [40 CFR 52.21] of the draft Significant Source Modification should be revised to read as follows:

- (a) The source shall operate the caustic scrubber **at all times when general process Tank 24 is emitting SO₂, and shall operate the recuperative regenerative** thermal oxidizer (RTO) or condensers at all times when general process Tank 24 is in operation **emitting VOC.**
- (c)(1) the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO), the combustion chamber shall maintain a minimum operating temperature **of 1600°F, or the temperature determined by a performance test during the most recent stack tests,** to maintain at least 90% destruction of volatile organic compounds, or
- (c)(2) the condensers ~~shall maintain a maximum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds,~~ **the outlet gas temperature shall be equal to or less than that specified by 326 IAC 8-5-3, see condition D.1.2.**

Response 28:

Condition D.1.1(a) has been modified to require that the source operate the caustic scrubber when Tank 24 is emitting SO₂, and operate the RTO or condenser when Tank 24 is emitting VOC. Condition D.1.1(c)(1) has been modified to mention either the Regenerative Thermal Oxidizer's operational temperature or the temperature determined by the most recent stack test on identical equipment. D.1.1(c)(2) shall not be modified, as D.1.2 (b) requires that the VOC emissions from tank 24 shall be controlled by the Regenerative Thermal Oxidizer system identified as RTO1 or RTO2 and shall be reduced by at least ninety percent (90%). The changes to Condition D.1.1 are as follows:

- (a) The source shall operated the caustic scrubber **at all times when general process Tank 24 is emitting SO₂, and shall operate the recuperative regenerative** thermal oxidizer (RTO) or condensers at all times when general process Tank 24 is ~~in operation~~ **emitting VOC**.
- (b) When the SO₂ emissions from Tank 24 are controlled by the caustic scrubber, the pressure drop shall be maintained within the range of 1.0 to 3.0 inches of water or a range determined by a performance test to maintain at least 95% destruction of SO₂,
- (c) When the VOC emissions from the one (1) general process Tank 24 are controlled by
 - (1) the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO), the combustion chamber shall maintain a minimum operating temperature of **1600°F, or the temperature determined by a performance test during the most recent stack tests**, to maintain at least 90% destruction of volatile organic compounds, or
 - (2) the condensers shall maintain a maximum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds.

To demonstrate that the caustic scrubber, regenerative thermal oxidizer (RTO) or condensers are utilized when SO₂ or VOC are emitted, the following record keeping requirements have been added to Condition D.1.10 (Record Keeping Requirements) of the permit:

- (c) **To document compliance with Conditions D.1.1 and D.1.7, the Permittee shall maintain the following:**
 - (1) **records of the time during which the caustic scrubber, RTO or condenser serving Tank 24 were not operated;**
 - (2) **records of the reason that the caustic scrubber, RTO or condenser serving Tank 24 were not operated.**
- ~~(e)~~(d) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

Comment 29:

Condition D.1.2 Miscellaneous Operation; Synthesized Pharmaceutical Manufacturing [326 IAC 8-5-3] of the draft Significant Source Modification should be revised to read as follows for clarification:

1. Pursuant to 326 IAC 8-5-3 the ~~following~~ outlet gas temperature shall not exceed the following when using condensers to control the VOC emissions from tank 24;
~~(2) If surface condensers are used, the condenser outlet gas temperature must not exceed:~~
 - ~~(A) (1)~~ minus twenty-five degrees...
 - ~~(B) (2)~~ minus fifteen degrees...
 - ~~(C) (3)~~ zero degrees...
 - ~~(D) (4)~~ ten degrees...
 - ~~(E) (5)~~ twenty-five degrees...~~(2) (6)~~ The vapor pressures listed above shall be measured at twenty degrees Celsius (20°C).
 - ~~(3) (7)~~ If the equivalent control identified as RTO1 or RTO2 is used, the VOC emissions must be reduced by at least as much as they would be by using a surface condenser which meets the requirements of ~~clause (A)~~ **conditions (1) through (5) as applicable.**
- ~~(b) VOC emissions from tank 24 shall be controlled by the Regenerative Thermal Oxidizer system identified as RTO1 or RTO2 and shall be reduced:~~
~~(3) by at least ninety percent (90%).~~
- ~~(c) The owner or operator of a synthesized pharmaceutical facility shall enclose all centrifuges...more at twenty degrees Celsius (20°C).~~
- ~~(d)(b)~~ Pursuant to...
- ~~(e)(c)~~ Pursuant to 326 IAC 8-5-3(b)(6), the Permittee shall repair all visible leaks from which a liquid, containing VOC, **can be observed running or dripping.** The repair...

(Note: (b) is redundant to (a)(7) and 326 IAC 8-5-3 only requires that which is stated in (a)(7) – not 90%, (c) is not applicable to this process tank.

Response 29:

Condition D.1.2(b) is not redundant to Condition D.1.2(a)(7), as 326 IAC 8-5-3 (b)(2) requires VOC emissions from production equipment exhaust systems located at new sources in any county construction of which commences after July 1, 1990 shall be reduced by at least 90% if emissions are three hundred thirty pounds per day or more of VOC. D.1.2(e) has been revised to include additional language from 326 IAC 8-5-3(b)(6). The following changes have been made to the permit for clarification:

- (a) Pursuant to 326 IAC 8-5-3 the ~~following~~ outlet gas temperature shall not exceed the following when using condensers to control the VOC emissions from ~~tank~~**Tank 24**:
~~(1) If surface condensers are used, the condenser outlet gas temperature must not exceed:~~
 - ~~(A)(1)~~ minus twenty-five degrees Celsius (-25EC) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals (five and eight-tenths (5.8) pounds per square inch);
 - ~~(B)(2)~~ minus fifteen degrees Celsius (-15EC) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals (two and nine-tenths (2.9) pounds per square inch);
 - ~~(C) (3)~~ zero degrees Celsius (0EC) when condensing VOC of vapor pressure

- greater than ten (10) kiloPascals (one and five-tenths (1.5) pounds per square inch);
- ~~(D)~~ **(4)** ten degrees Celsius (10EC) when condensing VOC of vapor pressure greater than seven (7) kiloPascals (one (1) pound per square inch); or
- ~~(E)~~ **(5)** twenty-five degrees Celsius (25EC) when condensing VOC of vapor pressure greater than three and five-tenths (3.5) kilo Pascals (five-tenths (0.5) pound per square inch).
- ~~(2)~~ **(6)** The vapor pressures listed above shall be measured at twenty degrees Celsius (20EC).
- ~~(3)~~ **(7)** If the equivalent control identified as RTO1 or RTO2 is used, the VOC emissions must be reduced by at least as much as they would be by using a surface condenser which meets the requirements of ~~clause (A)~~ **conditions (1) through (6) as applicable.**
- (b) VOC emissions from tank 24 shall be controlled by the ~~Re recuperative~~ **Regenerative** Thermal Oxidizer system identified as RTO1 or RTO2 and shall be reduced:
- (1) by at least ninety percent (90%).
- ~~(c)~~ ~~The owner or operator of a synthesized pharmaceutical facility shall enclose all centrifuges, rotary vacuum filters, and other filters having an exposed liquid surface, where the liquid contains VOC and exerts a total VOC vapor pressure of three and five tenths (3.5) kiloPascals (five-tenths (0.5) pounds per square inch) or more at twenty degrees Celsius (20EC).~~
- ~~(d)~~**(c)** Pursuant to 326 IAC 8-5-3(b)(5), the Permittee shall install covers on all in process tanks that contain volatile organic compound. These covers shall be kept closed, unless production sampling, maintenance, or inspection procedures require operator access.
- ~~(e)~~ **(d)** Pursuant to 326 IAC 8-5-3(b)(6), the Permittee shall repair all visible leaks from which a liquid, containing VOC, **can be observed running or dripping.** The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

Comment 30:

Condition D.1.3 Leak Detection and Repair Requirements [326 IAC 20] [40 CFR Part 63, Subparts H & I] of the draft Significant Source Modification should be deleted for the following reason:

Condition D.1.3 is redundant of Condition D.1.9.

Response 30:

Condition D.1.9 duplicates the language used in Condition D.1.3 of the Emission Limitations and Standards section. Condition D.1.3 has been modified as follows to clarify which pollutants are reduced by the LDAR program, and to remove the Compliance Monitoring Requirements. The changes to the permit are as follows:

That the owner or operator shall implement the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management, to reduce fugitive **methylene chloride or carbon tetrachloride** emissions from processes that use methylene chloride **or carbon tetrachloride**. ~~If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to~~

~~implementation.~~

Condition D.1.9 has been modified as follows to clarify which pollutants are reduced by the LDAR program. The changes to the permit are as follows:

That the owner or operator shall implement the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management, to reduce fugitive **methylene chloride or carbon tetrachloride** emissions from processes that use methylene chloride **or carbon tetrachloride**. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.

Comment 31:

Condition D.1.5, Testing Requirements [326 IAC 2-7-6(1), (6)] [326 IAC 2-1.1-11], of the draft Significant Source Modification should be revised to read as follows:

The Permittee is not required to test this facility by this permit. **The testing required for this facility will be deferred and shall follow the schedule in the Title V Permit, to determine compliance with 326 IAC 8-5-3.** However, IDEM may require...

Response 31:

The testing required for this facility will be deferred and shall follow the schedule in the Title V Permit, to determine compliance with 326 IAC 8-5-3. The following changes have been made to Condition D.1.5 (Testing Requirements):

The Permittee is not required to test this facility by this permit. **The testing required for this facility will be deferred and shall follow the schedule in the Title V Permit, to determine compliance with 326 IAC 8-5-3.** However, IDEM may require compliance testing when necessary to determine if the facility is in compliance. If testing is required by IDEM, compliance with the VOC and SO₂ limits specified in Conditions D.1.1 and D.1.2 shall be determined by a performance test conducted in accordance with Section C - Performance Testing.

Comment 32:

Condition D.1.6 Volatile Organic Compounds (VOC) of the draft Significant Source Modification should be deleted for the following reasons:

326 IAC 8-1-4(a)(3) refers to testing for determining the composition of coatings as applied – Gen'l Tank 24 will not be used in the application of coatings.

326 IAC 8-1-2(a) refers to the compliance methods available for use in meeting emission limitations – Gen'l Tank 24 is subject to 326 IAC 8-5-3 which provides specific compliance methods available for this facility. These methods are already included in Condition D.1.2 Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing.

Response 32:

Condition D.1.6 has been deleted from the permit as there are no applicable Emission Limitations or Standards requiring record keeping of VOC content . The remaining conditions have been renumbered and the changes to the permit are as follows:

~~D.1.6 Volatile Organic Compounds (VOC)~~

~~Compliance with the VOC content and usage limitations contained in Condition D.1.2 and D.1.3 shall be determined pursuant to 326 IAC 8-1-4(a)(3) and 326 IAC 8-1-2(a) using formulation data supplied by the coating manufacturer. IDEM, OAM, reserves the authority to determine compliance using Method 24 in conjunction with the analytical procedures specified in 326 IAC 8-1-4.~~

Comment 33:

Condition D.1.7 VOC Emissions of the draft Significant Source Modification should be deleted for the following reasons:

Proposed Condition D.1.7 is typically used as the compliance demonstration method in coating source modifications.

Response 33:

Condition D.1.7, now condition D.1.6, is required to show compliance with D.1.1 and D.1.2, as operation of the RTO shows compliance. Therefore, Condition D.1.7, now condition D.1.6, has been modified to include Conditions D.1.1 and D.1.2 and to state that the operational parameters of the control device show compliance. The changes to the permit as follows:

~~D.1.76 VOC Emissions~~

~~Compliance with Condition **D.1.1** and D.1.2 shall be demonstrated within 30 days of the end of each month based on the ~~total volatile organic compound usage~~ **Tank 24 control device operational parameters** for the most recent month.~~

Comment 34:

Condition D.1.8, Parametric Monitoring, of the draft Significant Source Modification should be revised to read as follows:

- (a) The Permittee shall ~~record~~ monitor the total static pressure drop across the scrubber used in conjunction with ~~tank Tank 24~~, at least once weekly when ~~tank Tank 24~~ is in operation when venting to the atmosphere ~~emitting SO₂~~. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, ~~the~~ The pressure drop across the scrubber shall be maintained within the range of 1.0 and 3.0 inches of water or a range established during the latest stack test ~~at less than 1 inch of water per foot of packing~~. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.
- (b) The Permittee shall record the operating temperature of the ~~Recuperative Regenerative~~ Thermal Oxidizers used in conjunction with ~~tank Tank 24~~, at least once weekly when ~~tank Tank 24~~ is in operation when venting to the atmosphere ~~emitting VOC~~. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the ~~The~~ **Recuperative Regenerative** Thermal Oxidizers shall be maintained at an operating temperature of at least 1,600 °F or a ~~range~~ **temperature** established ~~determined~~ during the latest ~~most recent~~ stack test ~~to maintain at least 90% destruction of volatile organic compounds~~. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.

(See Comment on C.11 for comments on the Compliance Response Plan, the proposed scrubber pressure drop range is consistent with A157-6698 (10/9/96), Amendment to CP157-5120 (3/27/96))

Response 34:

The regulatory authority for and the essential elements of a compliance monitoring plan were clarified in IDEM's Compliance Monitoring Guidance, in May 1996. IDEM originally placed all the preventive maintenance requirements in the permit section titled "Preventive Maintenance Plan." Under that section the permittee's Preventive Maintenance Plan (PMP) had to set out requirements for the inspection and maintenance of equipment both on a routine basis and in response to monitoring. Routine maintenance was a set schedule of inspections and maintenance of the equipment. The second was inspection and maintenance in response to monitoring that showed that the equipment was not operating in its normal range. This monitoring would indicate that maintenance was required to prevent the exceedance of an emission limit or other permit requirement. The maintenance plan was to set out the "corrective actions" that the permittee would take in the event an inspection indicated an "out of specification situation," and also set out the time frame for taking the corrective action. In addition, the PMP had to include a schedule for devising additional corrective actions for out of compliance situations that the source had not predicted in the PMP. All these plans, actions and schedules were part of the Preventive Maintenance Plan, with the purpose of maintaining the permittee's equipment so that an exceedance of an emission limit or violation of other permit requirements could be prevented. If further explanation of this matter is necessary, please see the response to comment 23 for more information.

Condition D.1.8 (now Condition D.1.7) has been modified to require that the source operate the caustic scrubber when Tank 24 is emitting SO₂, and operate the RTO or condenser when Tank 24 is emitting VOC. The following descriptive changes have been made to Condition D.1.8 (now Condition D.1.7), Parametric Monitoring:

- (a) The Permittee shall ~~record~~ monitor the total static pressure drop across the scrubber used in conjunction with ~~tank Tank~~ Tank 24, at least once weekly when ~~tank Tank~~ Tank 24 is in operation when venting to the atmosphere **emitting SO₂**. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the scrubber shall be maintained ~~within the range of 1.0 and 3.0 inches of water or a range established during the latest stack test~~ **at less than 1 inch of water per foot of packing**. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.
- (b) The Permittee shall record the operating temperature of the ~~Recuperative~~ **Regenerative** Thermal Oxidizers used in conjunction with ~~tank Tank~~ Tank 24, at least once weekly when ~~tank Tank~~ Tank 24 is in operation when venting to the atmosphere **emitting VOC**. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the ~~Recuperative~~ **Regenerative** Thermal Oxidizers shall be maintained at an operating temperature of at least 1,600 °F or a ~~range temperature established~~ **determined** during the ~~latest~~ **most recent** stack test **to maintain at least 90% destruction of volatile organic compounds**. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.

Comment 35:

Condition D.1.9 40 CFR Part 63, Subpart H and I (National Emissions Standard for Hazardous Air Pollutants) should be revised to read as follows:

That the owner or operator...to reduce fugitive ~~VOC~~ emissions from processes that use methylene chloride **or carbon tetrachloride**. If it is not feasible...

Response 35:

Tank 24 is subject to National Emissions Standard for Hazardous Air Pollutants 40 CFR 63.190(b)(5) Subparts H and I when Methylene Chloride or carbon tetrachloride is used for pharmaceutical synthesis operations. The Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management, will fulfill the requirements of National Emissions Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H as required by the National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes subject to the Negotiate Regulation for Equipment Leaks, 40 CFR Part 63, Subpart I. To clarify which pollutants Subparts H and I apply to, the following changes have been made to Condition D.1.9 (now D.1.8) the permit:

D.1.98 40 CFR Part 63, Subpart H and I (National Emissions Standard for Hazardous Air Pollutants)

That the owner or operator shall implement the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management, to reduce fugitive **methylene chloride or carbon tetrachloride** emissions from processes that use methylene chloride **or carbon tetrachloride**.

Comment 36:

Condition D.1.10, 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production), should be revised to read as follows:

The General Tank 24 is subject to the ~~proposed~~ National Emissions Standard for Hazardous Air Pollutants 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production). **This process tank**, and shall be in compliance with this NESHAP ~~when it is promulgated by the year 2001~~ **by the compliance date**.

(Note: The rule has been promulgated and has a current compliance date of September 21, 2001. However, the rule is in litigation and will be repromulgated as a result.)

Response 36:

The permit has been revised as follows:

The General Tank 24 is subject to the ~~proposed~~ National Emissions Standard for Hazardous Air Pollutants 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production). **This process tank**, and shall be in compliance with this NESHAP ~~when it is promulgated by the year 2001~~ **by the compliance date**.

Comment 37:

Condition D.1.11 Record Keeping Requirements needs to be clarified for the following reason:

There is a reference to "in accordance with (1) through (6) below". However, there are no conditions (1) through (6) under (a).

Comment 38:

Condition D.1.11 Record Keeping Requirements should be revised to read as follows:

- (b) An owner or operator of the facility covered by this permit, when using ~~the~~ methylene chloride or carbon tetrachloride, shall comply with the record keeping requirements provided in ~~National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H as required by the National Emission Standards for Organic Hazardous Air Pollutant for Certain Processes subject to the Negotiated Regulation for Equipment Leaks, 40 CFR Part 63, Subpart I~~ **the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management.**
- (c) To document compliance with Condition D.1.8, the Permittee shall maintain the following:
 - (4) ~~Daily~~ **Weekly** records of the operating temperature **of the Regenerative Thermal Oxidizers** during normal operation when ~~venting to the atmosphere~~ **Tank 24 is emitting VOC as pertains to the Recuperative Thermal Oxidizers.**
 - (5) ~~Daily~~ **Malfunction** records of the **scrubber** inlet and outlet differential static pressure during normal operation when ~~venting to the atmosphere as pertains to the scrubber.~~
 - (6) ~~Documentation...~~
 - (7) ~~Operation...~~
 - (8) ~~Quality...~~
 - (9) ~~Operator...~~
 - (10) ~~Manufacturer's...~~
 - (11) ~~Equipment...~~
 - (12) ~~Documentation...~~

(Note: Conditions (c)(3) – (c)(9) are vague and do not provide a clear explanation on the kind of information that would satisfy these conditions)

Response 37 & 38:

Tank 24 is subject to National Emissions Standard for Hazardous Air Pollutants 40 CFR 63.190(b)(5) Subparts H and I when Methylene Chloride or carbon tetrachloride is used for pharmaceutical synthesis operations. The Leak Detection and Repair (LDSR) Program proposed by Eli Lilly will be sufficient to replace the requirements of Subparts H and I.

Conditions D.1.1 and D.1.2 are necessary to show that the conditions needed to make Prevention of Significant Deterioration (PSD) rules, 326 IAC 2-2 and 40 CFR 52.21, not applicable to this modification have been met. The reporting required in Condition D.1.12(c)(4) [now D.1.12(b)(4)] shall not be removed as they provide compliance with 326 IAC 2-7-5(3)(B)(i)(DD) and 326 IAC 2-7-5(3)(B)(i)(FF). If a Permittee failed to keep records of monitoring required by the permit, this would be a deviation. The following changes have been made to the permit:

- ~~(a)~~ To document compliance with Conditions D.1.1 and D.1.2, the Permittee shall maintain records in accordance with (1) through (6) below. Records maintained for (1) through (6) shall be taken weekly and shall be complete and sufficient to establish compliance with the VOC and SO₂ emission limits established in Conditions D.1.1 and D.1.2.
- ~~(b)~~(a) An owner or operator of the facility covered by this permit, when using the methylene chloride or carbon tetrachloride, shall comply with the record keeping requirements provided in National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H as required by the National Emission Standards for Organic Hazardous Air Pollutant for Certain Processes subject to the Negotiated Regulation for Equipment Leaks, 40 CFR Part 63, Subpart I **the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management. The LDAR Program will fulfill the requirements of National Emissions Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H as required by the National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes subject to the Negotiate Regulation for Equipment Leaks, 40 CFR Part 63, Subpart I.**
- ~~(c)~~(b) To document compliance with Conditions **D.1.1, D.1.2 and** D.1.8, the Permittee shall maintain the following:
- (1) ~~Daily~~**Weekly** records of the operating temperature during normal operation when venting to the atmosphere as pertains to the ~~Recuperative~~**Regenerative** Thermal Oxidizers.

Comment 39:

Condition D.1.12 Reporting Requirements should be revised to read as follows:

- ~~(a)~~ A quarterly summary of the information to...of the quarter being reported.
- (b) Each owner or operator of a source shall submit the reports as required per ~~National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H as required by the National Emission Standards for Organic Hazardous Air Pollutant for Certain Processes subject to the Negotiated Regulation for Equipment Leaks, 40 CFR Part 63, Subpart I~~ **the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management.**

Response 39:

Tank 24 is subject to National Emissions Standard for Hazardous Air Pollutants 40 CFR 63.190(b)(5) Subparts H and I when Methylene Chloride or carbon tetrachloride is used for pharmaceutical synthesis operations. The Leak Detection and Repair (LDSR) Program proposed by Eli Lilly will be sufficient to replace the requirements of Subparts H and I. The following changes have been made to Condition D.1.12 (now D.1.11) of the permit:

- (b) Each owner or operator of a source shall submit the reports as required per ~~National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H as required by the National Emission Standards for Organic Hazardous Air Pollutant for Certain Processes subject to the Negotiated Regulation for Equipment Leaks, 40 CFR Part 63, Subpart I~~ **the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly and most recently approved by the Office of Air Management. The LDAR Program will fulfill the requirements of National Emissions Standards for Organic Hazardous Air Pollutants for Equipment Leaks, 40 CFR Part 63, Subpart H as required by the National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes subject to the Negotiate Regulation for Equipment Leaks, 40 CFR Part 63, Subpart I.**

Comment 40:

Part 70 Source Modification Certification form should be deleted due to the following reason:

The Significant Source Modification Approval is being issued pursuant to 326 IAC 2-7-10.5. Neither 326 IAC 2-7-4(f) or 326 IAC 2-7-5(3)(C) are applicable. There are no "Responsible Official" certification requirements for source modifications at sources without Title V permits.

Response 40:

The source is not subject to 326 IAC 2-7-4(f) or 326 IAC 2-7-5(3)(C), therefore the Part 70 Source Modification Certification form has been deleted from the permit, and the remaining pages have been renumbered.

Comment 41:

Part 70 Source Modification Quarterly Report form should be deleted.

Response 41:

The Part 70 Source Modification Quarterly Report form is necessary to show that the conditions needed to make Prevention of Significant Deterioration (PSD) rules, 326 IAC 2-2 and 40 CFR 52.21, not applicable to this modification have been met.

Comment 42:

Section Source Background and Description of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

Source Name: Eli Lilly and Company, **Tippecanoe Laboratories**
Source Location: 1650 Lilly Road, Shadeland, Indiana ~~47905~~ **47909**

The point source emissions from the process vessel may vent directly to RTO1 or RTO2, or it **they** may first vent to caustic scrubbers, process control condensers, vacuum sources, or through other process ~~vessel vessels~~ before going to... Also, in the event that RTO1 or RTO2 is unavailable, Lilly would continue manufacturing operations in the process vessel using other existing pollution control equipment that complies with 326 IAC 8-5-3 and ~~326 IAC 2-2~~. The carbon monoxide emissions from the ~~replacement~~ tank will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from the ~~replacement~~ tank will be ~~voluntarily~~ controlled by caustic scrubbers. The nitrogen oxides emissions from the ~~replacement~~ tank will be voluntarily controlled by caustic scrubbers.

(326 IAC 2-2 does not apply to Tank 24 – see Condition D.1.1. This is a new tank installation, not a tank replacement. Also, the conditions of this permit will require that sulfur dioxide emissions are controlled by the scrubber and thus will not be "voluntarily" controlled.)

Response 42:

The following revisions have been made to the Technical Support Document under Compliance Requirements (**bolded** language has been added, the language with a ~~line~~ through it has been deleted). The OAM prefers that the Technical Support Document reflect the permit that was on public notice. Changes to the permit or technical support material that occur after the public notice are documented in this Addendum to the Technical Support Document. This accomplishes the desired result of ensuring that these types of concerns are documented and part of the record regarding this permit decision.

The source name has been revised throughout the TSD and Significant Source Modification to refer to Eli Lilly and Company, Tippecanoe Laboratories, and the zip code has been revised.

The source is already a major PSD source. This modification to the source is determined to be a minor PSD modification. This is because the source has accepted the use of controls to reduce VOC and SO₂ emissions. The use of these controls will prevent 326 IAC 2-2 and 40 CFR 52.21 from being applicable.

The emissions of SO₂ emissions are not voluntarily controlled and have been clarified to remove the words "voluntary". Tank 24 is not a replacement tank, and the word "replacement" has been removed from the unit description. The changes to the permit have been made as follows:

Source Name: Eli Lilly and Company, **Tippecanoe Laboratories**
Source Location: 1650 Lilly Road, Shadeland, Indiana ~~47905~~ **47909**

The unit description has been revised as follows:

- (a) One (1) general process tank with a ~~maximum~~ **nominal** capacity of 4,000 gallons, designated as ~~tank~~ **Tank 24**, located in an existing building designated as T100, and **capable of being** controlled by the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO) or condenser for VOC emissions, ~~and or by~~ an existing caustic scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and caustic scrubbers, respectively.

The point source emissions from the process vessel may vent directly to RTO1 or RTO2, or if **they** may first vent to caustic scrubbers, process control condensers, vacuum sources, or through other process ~~vessel~~ **vessels** before going to RTO1 or RTO2. If venting the process vessel to RTO1 or RTO2 would cause a safety concern, the process vessel may vent to an alternative pollution control device. Also, in the event that RTO1 or RTO2 is unavailable, Lilly ~~would~~ **may** continue manufacturing operations in the process vessel using other existing pollution control equipment that complies with 326 IAC 8-5-3 ~~and 326 IAC 2-2~~. The carbon monoxide emissions from the ~~replacement~~ tank will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from the ~~replacement~~ tank will be ~~voluntarily~~ controlled by caustic scrubbers. The nitrogen oxides emissions from the ~~replacement~~ tank will be voluntarily controlled by caustic scrubbers.

Comment 43:

The table in the section Potential to Emit of Modification of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

Hydrochloric Acid* ~~48.00~~ **47.54**

Response 43:

The Potential to Emit of Modification table on page 3 of 8 of the Technical Support Document, has been revised as follows:

Hydrochloric Acid* ~~48.00~~ **47.54**

Comment 44:

Section County Attainment Status of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

- (c) Fugitive Emissions
Since this type of operation is not one of the 28 listed source categories under 326 IAC 2-2 and since there are no applicable New Source Performance Standards that were in effect on August 7, 1980, the fugitive **PM VOC** emissions are not counted toward determination of PSD and Emission Offset applicability.

Response 44:

The language referring to fugitive PM emissions on page 3 of 8 of the TSD has been deleted. This source is in 1 of the 28 listed source categories as it has potential PSD emissions of 250 tons per year or more of any air pollutant subject to regulation under the Clean Air Act. The changes to the TSD are as follows:

- ~~(c) Fugitive Emissions
Since this type of operation is not one of the 28 listed source categories under 326 IAC 2-2 and since there are no applicable New Source Performance Standards that were in effect on August 7, 1980, the fugitive PM emissions are not counted toward determination of PSD and Emission Offset applicability.~~

Comment 45:

The Source Status of the Technical Support Document (TSD) of the draft Significant Source Modification should be clarified due to the following reason:

- (b) These emissions are based upon the 1988 Annual Air Emission Inventory and Emissions Statement.

Question – are the emissions in the table suppose to equal those in our 1988 Annual Air Emission Inventory or 1998 Emissions Statement (numbers are very close to 1998 Emissions Statement Data, but not exactly)?

Response 45:

The emissions listed on page 4 of 8 of the TSD are emissions are based upon the 1998 Annual Air Emission Inventory and Emissions Statement, on record at IDEM. The TSD has been revised to correct the year of emission inventory. The changes the Source Status, on page 4 of 8 of the TSD, are as follows:

- (b) These emissions are based upon the ~~1988~~**1998** Annual Air Emission Inventory and Emissions Statement.

Comment 46:

Section Federal Rule Applicability of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

- (a) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.480, Subpart VV. – Standards of Performance for Equipment Leaks of VOC in the

Synthetic Organic Chemical Manufacturing Industry (SOCMI)), because ~~the tank has a design capacity less than 1000 MG/year~~ **this operation does not involve the production of any chemical or compound listed in this NSPS as a product, co-product, by-product or intermediate product.**

- (b) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.610, Subpart III – Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes), because ~~the tank is not an air oxidation unit~~ **this operation does not involve the production of any chemical or compound listed in this NSPS as a product, co-product, by-product or intermediate product.**
- (c) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.660, Subpart NNN – Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations), because ~~the tank is operated as a batch reactor~~ **this operation does not involve the production of any chemical or compound listed in this NSPS as a product, co-product, by-product or intermediate product.**
- (d) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.700, Subpart RRR – Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes), because ~~the tank is operated as a batch reactor~~ **this operation does not involve the production of any chemical or compound listed in this NSPS as a product, co-product, by-product or intermediate product.**

Response 46:

The discussion of the Federal Regulations, on pages 4 and 5 of 8 of the TSD, have been revised to clarify the reason why Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60. Subpart VV, III, NNN, or RRR).

- (a) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.110b, Subpart Kb - Standards of Performance for Volatile Organic Liquid Storage Vessels), because ~~the tank is not used for VOC storage purposes~~ **this operation does not involve the production of any chemical or compound listed in this NSPS as a product, co-product, by-product or intermediate product.**
- (b) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.480, Subpart VV - Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemical Manufacturing Industry (SOCMI)), because ~~the tank has a design capacity less than 1000 Mg/year~~ **this operation does not involve the production of any chemical or compound listed in this NSPS as a product, co-product, by-product or intermediate product.**
- (c) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.610, Subpart III, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes), because ~~the tank is not an air oxidation unit~~ **this operation does not involve the production of any chemical or compound listed in this NSPS as a product, co-product, by-product or intermediate product.**

- (d) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.660, Subpart NNN, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations), because ~~the tank is operated as a batch reactor.~~ **this operation does not involve the production of any chemical or compound listed in this NSPS as a product, co-product, by-product or intermediate product.**
- (e) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.700, Subpart RRR, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes), because ~~the tank is operated as a batch reactor.~~ **this operation does not involve the production of any chemical or compound listed in this NSPS as a product, co-product, by-product or intermediate product.**

Comment 47:

Section Federal Rule Applicability of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

- (c) The General Tank 24 is subject to the ~~proposed~~ National Emissions Standard for Hazardous Air Pollutants 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) **which was promulgated on September 21, 1998. This process tank,** and shall be in compliance with this NESHAP ~~when it is promulgated by the year 2001~~ **by the compliance date.**

(Note: The rule has been promulgated and has a current compliance date of September 21, 2001. However, the rule is in litigation and will be repromulgated as a result. This text is in the second (c) in this section.)

Response 47:

The language used in the discussion of the applicability of Subpart GGG has been revised to clarify that the rule has been promulgated and has a current compliance date of September 21, 2001. However, the rule is in litigation and will be repromulgated as a result. The changes to the permit are as follows:

- (c) The General Tank 24 is subject to the ~~proposed~~ National Emissions Standard for Hazardous Air Pollutants 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) **which was promulgated on September 21, 1998. This process tank,** and shall be in compliance with this NESHAP ~~when it is promulgated by the year 2001~~ **by the compliance date.**

Comment 48:

Section State Rule Applicability – Individual Facilities, 326 IAC 2-2 (Prevention of Significant Deterioration) of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

- (a) The source shall operated the caustic scrubber **at all times when general process Tank 24 is emitting SO₂, and shall operate the recuperative regenerative** thermal oxidizer (RTO) or condensers at all times when general process Tank 24 is ~~in operation~~ **emitting VOC.**
- (b) When the SO₂ emissions from Tank 24 are controlled by the caustic scrubber, the pressure drop shall be maintained ~~within the range of 1.0 and 3.0 inches of water or a range determined by a performance test to maintain at least 95% destruction of SO₂ at~~ **less than 1 inch of water per foot of packing.**

- (c)(1) the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO), the combustion chamber shall maintain a minimum operating temperature **of 1600°F, or the temperature determined by a performance test during the most recent stack tests**, to maintain at least 90% destruction of volatile organic compounds, or
- (c)(2) the condensers ~~shall maintain a maximum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds,~~ **the outlet gas temperature shall be equal to or less than that specified by 326 IAC 8-5-3, see condition D.1.2.**

Response 48:

The caustic scrubber must operate only when the Tank is emitting SO₂, and the regenerative thermal oxidizer (RTO) must operate only when the tank is emitting VOC. The following changes have been made to the permit to correct the pressure drop range and to correctly list the Regenerative Thermal Oxidizer. The changes to the TSD are as follows:

326 IAC 2-2 (Prevention of Significant Deterioration)

The existing source is a major source. Therefore, any modification to this source which has the potential to emit of any of the criteria pollutants greater than the major modification thresholds, would be subject to the requirements of 326 IAC 2-2.

- (a) The source shall operated the caustic scrubber **at all times when general process Tank 24 is emitting SO₂, and shall operate the recuperative regenerative** thermal oxidizer (RTO) or condensers at all times when general process Tank 24 is ~~in operation~~ **emitting VOC**.
- (b) When the SO₂ emissions from Tank 24 are controlled by the caustic scrubber, the pressure drop shall be maintained ~~within the range of 1.0 to 3.0 inches of water~~ **at less than 1.0 inch of water per foot of packing** or a range determined by a performance test to maintain at least 95% destruction of SO₂,
- (c) When the VOC emissions from the one (1) general process Tank 24 are controlled by
 - (1) the existing ~~Recuperative~~ **Regenerative** Thermal Oxidizer (RTO), the combustion chamber shall maintain a minimum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds, or
 - (2) the condensers shall maintain a maximum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds.

These conditions are necessary to make Prevention of Significant Deterioration (PSD) rules, 326 IAC 2-2 and 40 CFR 52.21, not applicable to this modification.

Comment 49:

Section State Rule Applicability – Individual Facilities, 326 IAC 2-1-3.4 (New Source Toxics Control) of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

326 IAC 2-1-3.4 (New Source Toxics Control) does not apply to the tank because the tank is specifically regulated by 40 CFR Part 63 Subpart H and ~~H~~ **GGG** (NESHAP).

Response 49:

The following changes have been made to the TSD to correct the rule citation for New Source Toxics Control and to include Subpart GGG:

326 IAC ~~2-1-3.4~~ **2-4.1-1** (New Source Toxics Control):

326 IAC ~~2-4-3.4~~ **2-4.1-1** (New Source Toxics Control) does not apply to the tank because the tank is specifically regulated by 40 CFR Part 63 Subparts H, ~~and I~~ **and GGG** (NESHAP).

Comment 50:

Section State Rule Applicability – Individual Facilities, 326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations) of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

- (3) If the equivalent control identified as RTO1 or RTO2 is used, the VOC emissions must be reduced by at least as much as they would be by using a surface condenser which meets the requirements of ~~clause (A)~~ **Conditions (1)(A) through (1)(E) as applicable.**

Response 50:

The following changes have been made to the TSD:

- (3) If the equivalent control identified as RTO1 or RTO2 is used, the VOC emissions must be reduced by at least as much as they would be by using a surface condenser which meets the requirements of ~~clause (A)~~ **Conditions (1)(A) through (1)(E) as applicable.**

Comment 51:

Section Compliance Determination Requirements of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

- (a)(1) The Permittee shall ~~record~~ **monitor** the total static pressure drop across the scrubber used in conjunction with ~~tank Tank~~ **Tank 24**, at least once weekly when ~~tank Tank~~ **Tank 24** is in operation when venting to the atmosphere **emitting SO₂**. ~~Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the~~ **The** pressure drop across the scrubber shall be maintained ~~within the range of 1.0 and 3.0 inches of water or a range established during the latest stack test~~ **at less than 1 inch of water per foot of packing**. ~~The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.~~
- (a)(2) The Permittee shall record the operating temperature of the ~~Recuperative~~ **Regenerative** Thermal Oxidizers used in conjunction with ~~tank Tank~~ **Tank 24**, at least once weekly when ~~tank Tank~~ **Tank 24** is in operation when venting to the atmosphere **emitting VOC**. ~~Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the~~ **The** ~~Recuperative~~ **Regenerative** Thermal Oxidizers shall be maintained at an operating temperature of at least 1,600 °F or a ~~range~~ **temperature** established during the ~~latest~~ **most recent** stack test **to maintain at least 90% destruction of volatile organic compounds**. ~~The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.~~

(See Comment on C.11 for comments on the Compliance Response Plan, See Comment on D.1.7 & D.1.8 for comments on parametric monitoring)

- (a)(4) The proposed ~~replacement~~ process tank, General Tank 24 is subject to **the National Emissions Standard for Hazardous Air Pollutants** 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) **which was promulgated on September 21, 1998. This process tank, and** shall be in compliance with this NESHAP ~~by the year 2001~~ **by the compliance date.**

(Note: This is a new tank installation, not a tank replacement. Also, the rule has been promulgated and has a current compliance date of September 21, 2001. However, the rule is in litigation and will be repromulgated as a result.)

Response 51:

See response to comment 23 for an in-depth explanation of the Compliance Response Plan. (a)(4) has been changed to list the correct language:

- (a) The one (1) general process tank with a maximum capacity of 4,000 gallons, has applicable compliance monitoring conditions as specified below:
- (1) The Permittee shall ~~record~~ **monitor** the total static pressure drop across the scrubber used in conjunction with ~~tank Tank 24~~, at least once weekly when ~~tank Tank 24 is in operation when venting to the atmosphere emitting SO₂~~. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the scrubber shall be maintained ~~within the range of 1.0 and 3.0 inches of water or a range established during the latest stack test at~~ **less than 1 inch of water per foot of packing**. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.
 - (2) The Permittee shall record the operating temperature of the ~~Recuperative~~ **Regenerative** Thermal Oxidizers used in conjunction with ~~tank Tank 24~~, at least once weekly when ~~tank Tank 24 is in operation when venting to the atmosphere emitting VOC~~. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the ~~Recuperative~~ **Regenerative** Thermal Oxidizers shall be maintained at an operating temperature of at least 1,600 °F or a ~~range temperature established determined~~ during the ~~latest~~ **most recent** stack test **to maintain at least 90% destruction of volatile organic compounds**. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.

The instrument used for determining the pressure shall comply with Section C - Pressure Gauge Specifications, of this permit, shall be subject to approval by IDEM, OAM, and shall be calibrated at least once every six (6) months.

- (3) That the owner or operator shall implement the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly, most recently approved by the Office of Air Management, to reduce fugitive VOC emissions from processes that use methylene chloride. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.
- (4) The General Tank 24 is subject to the ~~proposed~~ National Emissions Standard for Hazardous Air Pollutants 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) **which was promulgated on September 21, 1998. This process tank, and** shall be in compliance with this NESHAP ~~when it is promulgated by the~~

~~year 2004~~ by the compliance date.

These monitoring conditions are necessary because the caustic scrubber and ~~Re recuperative~~ **Regenerative** Thermal Oxidizers for the one (1) general process tank with a maximum capacity of 4,000 gallons, must operate properly to ~~ensure compliance with~~ **make** 326 IAC 2-2 (Prevention of Significant Deterioration) **not applicable to this modification, and to ensure compliance with** 326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations), and 326 IAC 2-7 (Part 70).

Comment 52:

Compliance Determinations Requirements of the Technical Support Document (TSD) of the draft Significant Source Modification should be revised to read as follows:

These monitoring conditions are necessary because the caustic scrubber and Regenerative Thermal Oxidizers for the one (1) general process tank with a maximum capacity of 4,000 gallons, must operate properly to ~~ensure compliance with~~ **make** 326 IAC 2-2 (Prevention of Significant Deterioration) **not applicable to this modification, and to ensure compliance with** 326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations), and 326 IAC 2-7 (Part 70).

(326 IAC 2-2 is not applicable to this modification if the proposed process tank is in compliance with the PSD Minor Limit conditions in this Source Modification)

Response 52:

These monitoring conditions are necessary because the caustic scrubber and Regenerative Thermal Oxidizers for the one (1) general process tank with a maximum capacity of 4,000 gallons, must operate properly to ~~ensure compliance with~~ **make** 326 IAC 2-2 (Prevention of Significant Deterioration) **not applicable to this modification, and to ensure compliance with** 326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations), and 326 IAC 2-7 (Part 70).

Appendix A Comments

Comment 53:

Source Address: 1650 Lilly Road, Shadeland, Indiana ~~47905~~ **47909**
(Note: Update of recent zip code reassignment)

Response 53:

In Appendix A, pages 1 through 10, the zip code has been changed as follows:
Source Address: 1650 Lilly Road, Shadeland, Indiana ~~47905~~ **47909**

Comment 54:

The Uncontrolled Potential Emissions (tons/year) table of the draft Significant Source Modification should be revised to read as follows:

NO _x	62.27	6.78
VOC	8.30	62.27
CO	79.90	79.09

(Note: These corrections are necessary in both columns)

Comment 55:

The Controlled Potential Emissions (tons/year) table of the draft Significant Source Modification should be revised to read as follows:

CO ~~79.90~~ **79.09**

(Note: These corrections are necessary in both columns)

Response 54 & 55:

In Appendix A, page 1 of 10, the uncontrolled emissions listed in the emission summary has been revised to list the correct emissions from the source. In Appendix A, on page 1 of 10, the controlled emissions of Carbon Monoxide (CO) listed in the emission summary have been revised to state the correct controlled emissions of CO. The Potential To Emit of Modification on page 2 of 8 of the TSD lists the correct emissions from the source, and does not require revision.

The changes to the controlled emissions listed in the emission summary of Appendix A are as follows:

Uncontrolled Potential Emissions (tons/year)		
Emissions Generating Activity		
Pollutant	General Tank 24 Building T100	TOTAL
PM	0.00	0.00
PM10	0.00	0.00
SO2	121.20	121.20
NOx	62.27 6.78	62.27 6.78
VOC	8.30 62.27	8.30 62.27
CO	79.90 79.09	79.90 79.09
total HAPs	109.81	109.81
worst case single HAP	*62.27	*62.27
Total emissions based on rated capacity at 8,760 hours/year.		
Controlled Potential Emissions (tons/year)		
Emissions Generating Activity		
Pollutant	General Tank 24 Building T100	TOTAL
PM	0.00	0.00
PM10	0.00	0.00
SO2	6.06	6.06
NOx	6.78	6.78
VOC	8.30	8.30
CO	79.90 79.09	79.90 79.09
total HAPs	54.62	54.62
worst case single HAP	(HCl) 47.54	(HCl) 47.54
Total emissions based on rated capacity at 8,760 hours/year, after control.		
Worst case HAP may include any one of the following: Dimethyl Formamide, Ethylene Glycol, Ethylene Dichloride, Glycol Ethers, Hexane, Hydrochloric Acid, Methanol, Methyl Ethyl Ketone, Methylene Chloride, Phosgene, Toluene, Triethylamine, Xylenes		

**Indiana Department of Environmental Management
Office of Air Management**

**Technical Support Document (TSD) for a Part 70 Significant Source
Modification.**

Source Background and Description

Source Name:	Eli Lilly and Company
Source Location:	1650 Lilly Road, Shadeland, Indiana 47905
County:	Tippecanoe
SIC Code:	2834 & 2879
Operation Permit No.:	T157-6879-00006
Operation Permit Application Date:	October 10, 1996
Source Modification No.:	157-11031-00006
Permit Reviewer:	Phillip Ritz/EVP

The Office of Air Management (OAM) has reviewed a modification application from Eli Lilly and Company relating to the construction of the following emission units and pollution control devices:

- (a) One (1) general process tank with a maximum capacity of 4,000 gallons, designated as tank 24, located in an existing building designated as T100, and controlled by the existing Recuperative Thermal Oxidizer (RTO) or condenser for VOC emissions, and an existing caustic scrubber for SO₂ emissions. CO and NO_x emissions will be controlled voluntarily by existing RTOs and caustic scrubbers, respectively.

The point source emissions from the process vessel may vent directly to RTO1 or RTO2, or it may first vent to caustic scrubbers, process control condensers, vacuum sources, or through other process vessel before going to RTO1 or RTO2. If venting the process vessel to RTO1 or RTO2 would cause a safety concern, the process vessel may vent to an alternative pollution control device. Also, in the event that RTO1 or RTO2 is unavailable, Lilly would continue manufacturing operations in the process vessel using other existing pollution control equipment that complies with 326 IAC 8-5-3 and 326 IAC 2-2. The carbon monoxide emissions from the replacement tank will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from the replacement tank will be voluntarily controlled by caustic scrubbers. The nitrogen oxides emissions from the replacement tank will be voluntarily controlled by caustic scrubbers.

History

On June 3, 1999, Eli Lilly and Company submitted an application to the OAM requesting to add one (1) general process tank with a maximum capacity of 4,000 gallons, designated as tank 24, to their existing stationary source, chemical manufacturing operation that produces pharmaceutical preparation and agricultural chemicals. Eli Lilly and Company submitted a Part 70 permit application (T157-6879-00006) on October 10, 1996.

Enforcement Issue

There are no enforcement actions pending.

Stack Summary

Stack ID	Operation	Height (feet)	Diameter (feet)	Flow Rate (acfm)	Temperature (°F)
RTO1	General Tank TK24	125	9	98,000	170
or RTO2	General Tank TK24	125	9	98,000	125

Recommendation

The staff recommends to the Commissioner that the Part 70 Significant Source Modification be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on June 3, 1999.

Emission Calculations

See Appendix A of this document for detailed emissions calculations (Appendix A, pages 1 through 10.)

Potential To Emit of Modification

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as “the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA.”

This table reflects the PTE before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	0.00
PM-10	0.00
SO ₂	121.20
VOC	62.27
CO	79.09
NO _x	6.78

HAP's	Potential To Emit (tons/year)
Dimethyl Formamide*	62.27
Ethylene Glycol*	62.27
Ethylene Dichloride*	62.27
Glycol Ethers*	62.27
Hexane*	62.27
Hydrochloric Acid*	48.00
Methanol*	62.27
Methyl Ethyl Ketone*	62.27
Methylene Chloride*	62.27
Phosgene*	62.27
Toluene*	62.27
Triethylamine*	62.27
Xylenes*	62.27
TOTAL	109.81

*for this process vessel, acetone (a non-regulated VOC) was used as the solvent in the emission calculations and a 365-day year operating schedule was assumed to get a worst case potential emissions scenario for organic HAPs. Of the solvents most frequently used, acetone has the highest representative volatility.

Justification for Modification

The Part 70 Operating permit is being modified through a Part 70 Significant Source Modification. This modification is being performed pursuant to 326 IAC 2-7-10.5(f)(4), for any modification with a potential to emit greater than or equal to twenty-five (25) tons per year of any of the criteria pollutants.

County Attainment Status

The source is located in Tippecanoe County.

Pollutant	Status
PM-10	attainment
SO ₂	attainment
NO ₂	attainment
Ozone	attainment
CO	attainment
Lead	attainment

- (a) Volatile organic compounds (VOC) and oxides of nitrogen (NO_x) are precursors for the formation of ozone. Therefore, VOC and NO_x emissions are considered when evaluating the rule applicability relating to the ozone standards. Tippecanoe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NO_x emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.
- (b) Tippecanoe County has been classified as attainment or unclassifiable for all criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.
- (c) Fugitive Emissions
Since this type of operation is not one of the 28 listed source categories under 326 IAC 2-2 and since there are no applicable New Source Performance Standards that were in effect on August 7, 1980, the fugitive PM emissions are not counted toward determination of PSD and Emission Offset applicability.

Source Status

Existing Source PSD or Emission Offset Definition (emissions after controls, based upon 8760 hours of operation per year at rated capacity and/or as otherwise limited):

Pollutant	Emissions (tons/year)
PM	438.17
PM-10	438.17
SO ₂	970.34
VOC	188.35
CO	196.05
NO _x	418.96

- (a) This existing source is a major stationary source because an attainment regulated pollutant is emitted at a rate of 250 tons per year or more, and it is not one of the 28 listed source categories.
- (b) These emissions are based upon the 1988 Annual Air Emission Inventory and Emissions Statement.

Potential to Emit of Modification After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. The control equipment is considered federally enforceable only after issuance of this Part 70 source modification.

	Potential to Emit (tons/year)						
Process/facility	PM	PM-10	SO ₂	VOC	CO	NO _x	HAPs
One (1) general process tank with a maximum capacity of 4,000 gallons, designated as tank 24	0.00	0.00	6.06	8.30	79.09	6.78	54.62
Net Emissions	0.00	0.00	6.06	8.30	79.09	6.78	54.62
PSD Significant Level	25.00	15.00	40.00	40.00	100.00	40.00	N/A

This modification to an existing major stationary source is not major because the emissions increase is less than the PSD significant levels. Therefore, pursuant to 326 IAC 2-2, and 40 CFR 52.21, the PSD requirements do not apply.

Federal Rule Applicability

- (a) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.110b, Subpart Kb - Standards of Performance for Volatile Organic Liquid Storage Vessels), because the tank is not used for VOC storage purposes.

- (b) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.480, Subpart VV - Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemical Manufacturing Industry (SOCMI)), because the tank has a design capacity less than 1000 Mg/year.
- (c) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.610, Subpart III, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes), because the tank is not an air oxidation unit.
- (d) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.660, Subpart NNN, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations), because the tank is operated as a batch reactor.
- (e) Tank 24 is not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.700, Subpart RRR, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes), because the tank is operated as a batch reactor.

There are no other New Source Performance Standards (326 IAC 12) applicable to these tank.

- (a) Tank 24 is not subject to Emissions Standards for Hazardous Air Pollutants, 326 IAC 14 and 40 CFR Part 61, because no hazardous air pollutants covered under these rules are emitted from the tank.
- (b) Tank 24 is subject to National Emissions Standard for Hazardous Air Pollutants 40 CFR 63.190(b)(5) Subparts H and I when Methylene Chloride is used for pharmaceutical synthesis operations. Eli Lilly will comply with these requirements, with the implementation of Eli Lilly's Leak Detection and Repair (LDAR) Program when Methylene Chloride is used in the tank. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.
- (c) The General Tank 24 is subject to the proposed National Emissions Standard for Hazardous Air Pollutants 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production), and shall be in compliance with this NESHAP when it is promulgated by the year 2001

State Rule Applicability - Individual Facilities

326 IAC 2-2 (Prevention of Significant Deterioration)

The existing source is a major source. Therefore, any modification to this source which has the potential to emit of any of the criteria pollutants greater than the major modification thresholds, would be subject to the requirements of 326 IAC 2-2.

- (a) The source shall operate the caustic scrubber and recuperative thermal oxidizer (RTO) or condensers at all times when the one (1) general process Tank 24 is in operation,
- (b) When the SO₂ emissions from Tank 24 are controlled by the caustic scrubber, the pressure drop shall be maintained within the range of 1.0 to 3.0 inches of water or a range determined by a performance test to maintain at least 95% destruction of SO₂,

- (c) When the VOC emissions from the one (1) general process Tank 24 are controlled by
 - (1) the existing Recuperative Thermal Oxidizer (RTO), the combustion chamber shall maintain a minimum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds, or
 - (2) the condensers shall maintain a maximum operating temperature determined by a performance test to maintain at least 90% destruction of volatile organic compounds.

These conditions are necessary to make Prevention of Significant Deterioration (PSD) rules, 326 IAC 2-2 and 40 CFR 52.21, not applicable to this modification.

326 IAC 2-6 (Emission Reporting):

This facility is subject to 326 IAC 2-6 (Emission Reporting), because the source has the potential to emit VOC, NO_x, CO, PM, or SO₂ into the ambient air at levels equal to or greater than 100 tons/yr (attainment counties). Pursuant to this rule, the owner/operator of this facility must annually submit an emission statement of the facility. The annual statement must be received by July 1 of each year and must contain the minimum requirements as specified in 326 IAC 2-6-4.

326 IAC 2-1-3.4 (New Source Toxics Control):

326 IAC 2-1-3.4 (New Source Toxics Control) does not apply to the tank because the tank is specifically regulated by 40 CFR Part 63 Subpart H and I (NESHAP).

326 IAC 7 (Sulfur Dioxide Emission Limitations):

This rule does not apply because the tank is not a fuel combustion facilities.

326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations)

Tank 24 is subject to 326 IAC 8-5-3 (b)(1), (5), and (6) because it has potential uncontrolled VOC emissions greater than 15 lb/day and are used in pharmaceutical manufacturing by chemical synthesis. Pursuant to 326 IAC 8-5-3 the following outlet gas temperature when using condensers to control the VOC emissions from the one (1) general process Tank 24 shall not exceed the following:

- (1) If surface condensers are used, the condenser outlet gas temperature must not exceed:
 - (A) minus twenty-five degrees Celsius (-25°C) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals (five and eight-tenths (5.8) pounds per square inch);
 - (B) minus fifteen degrees Celsius (-15°C) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals (two and nine-tenths (2.9) pounds per square inch);
 - (C) zero degrees Celsius (0°C) when condensing VOC of vapor pressure greater than ten (10) kiloPascals (one and five-tenths (1.5) pounds per square inch);
 - (D) ten degrees Celsius (10°C) when condensing VOC of vapor pressure greater than seven (7) kiloPascals (one (1) pound per square inch); or
 - (E) twenty-five degrees Celsius (25°C) when condensing VOC of vapor pressure greater than three and five-tenths (3.5) kilo Pascals (five-tenths (0.5) pound per square inch).
- (2) The vapor pressures listed above shall be measured at twenty degrees Celsius (20°C).
- (3) If the equivalent control identified as RTO1 or RTO2 is used, the VOC emissions must be reduced by at least as much as they would be by using a surface condenser which meets the requirements of clause (A).

The minimum control efficiency required by 326 IAC 8-5-3 (b)(1) is around 90%. VOC emissions can be controlled by using either the condensers in series with RTO1 or RTO2, or RTO1 or RTO2 alone to meet the requirements of 326 IAC 8-5-3. Eli Lilly will typically use the existing RTO1 or RTO2 to control point source VOC emissions from the tank. RTO1 or RTO2, which has been demonstrated to achieve VOC removal efficiency in excess of 97%, will meet and exceed the requirements of 326 IAC 8-5-3 (b)(1). If RTO1 or RTO2 cannot be used due to safety issues, an alternative control device may be used as long as the conditions of 326 IAC 8-5-3 (b)(1) are met. An analysis to demonstrate the alternative controls are acceptable controls, will be done before such alternative controls are used. In the event that RTO1 or RTO2 is unavailable, Eli Lilly would like to continue manufacturing operations in the process tank using other existing equipment that complies with 326 IAC 8-5-3 (b)(1).

The process tank is equipped with tight fitting covers. As indicated by the applicant, the cover is closed at all times unless the production, sampling, inspection, or maintenance activities require access to the tank. Hence, it meets the requirements of 326 IAC 8-5-3 (b)(5).

Tank 24, located in Building T-100 standard operating procedures, as indicated by the applicant, is to repair all the visible equipment leaks as soon as possible. During the operation, process operators inspect tank and equipment (valves, flanges, etc.) for visible indications of leaks. Eli Lilly repairs all the visible liquid leaks containing a VOC as soon as the equipment is off line long enough to complete the repair. Hence, this procedure meets the requirements of 326 IAC 8-5-3 (b)(6). The results of performance testing required by CP 157-2593 can be used for this modification.

326 IAC 8-1-6 (BACT):

The requirement to reduce VOC emissions using Best Available Control Technology (BACT) does not apply to Tank 24 because the tank is subject to the requirements of 326 IAC 8-5-3.

No other 326 IAC 8 rules apply.

Compliance Requirements

Permits issued under 326 IAC 2-7 are required to ensure that sources can demonstrate compliance with applicable state and federal rules on a more or less continuous basis. All state and federal rules contain compliance provisions, however, these provisions do not always fulfill the requirement for a more or less continuous demonstration. When this occurs IDEM, OAM, in conjunction with the source, must develop specific conditions to satisfy 326 IAC 2-7-5. As a result, compliance requirements are divided into two sections: Compliance Determination Requirements and Compliance Monitoring Requirements.

Compliance Determination Requirements in Section D of the permit are those conditions that are found more or less directly within state and federal rules and the violation of which serves as grounds for enforcement action. If these conditions are not sufficient to demonstrate continuous compliance, they will be supplemented with Compliance Monitoring Requirements, also Section D of the permit. Unlike Compliance Determination Requirements, failure to meet Compliance Monitoring conditions would serve as a trigger for corrective actions and not grounds for enforcement action. However, a violation in relation to a compliance monitoring condition will arise through a source's failure to take the appropriate corrective actions within a specific time period.

The compliance monitoring requirements applicable to this modification are as follows:

- (a) The one (1) general process tank with a maximum capacity of 4,000 gallons, has applicable compliance monitoring conditions as specified below:

- (1) The Permittee shall record the total static pressure drop across the scrubber used in conjunction with tank 24, at least once weekly when tank 24 is in operation when venting to the atmosphere. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the scrubber shall be maintained within the range of 1.0 and 3.0 inches of water or a range established during the latest stack test. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.
- (2) The Permittee shall record the operating temperature of the Recuperative Thermal Oxidizers used in conjunction with tank 24, at least once weekly when tank 24 is in operation when venting to the atmosphere. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the Recuperative Thermal Oxidizers shall be maintained at an operating temperature of at least 1,600°F or a range established during the latest stack test. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.

The instrument used for determining the pressure shall comply with Section C - Pressure Gauge Specifications, of this permit, shall be subject to approval by IDEM, OAM, and shall be calibrated at least once every six (6) months.

- (3) That the owner or operator shall implement the Leak Detection and Repair (LDAR) Program proposed by Eli Lilly, most recently approved by the Office of Air Management, to reduce fugitive VOC emissions from processes that use methylene chloride. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.
- (4) The proposed replacement process tank, General Tank 24 is subject to 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) and shall be in compliance with this NESHAP by the year 2001.

These monitoring conditions are necessary because the caustic scrubber and Recuperative Thermal Oxidizers for the one (1) general process tank with a maximum capacity of 4,000 gallons, must operate properly to ensure compliance with 326 IAC 2-2 (Prevention of Significant Deterioration), 326 IAC 8-5-3 (Synthesized Pharmaceutical Manufacturing Operations), and 326 IAC 2-7 (Part 70).

Conclusion

The construction of this proposed modification shall be subject to the conditions of the attached proposed **Significant Source Modification to Part 70 Permit No. SSM157-11031-00006**.

Appendix A: Emission Calculations

Company Name: Eli Lilly & Co., Tippecanoe Laboratories
Address City IN Zip: 1650 Lilly Road, Shadeland, Indiana 47902
CP: 157-11031
Plt ID: 157-00006
Reviewer: PR/EVP
Date: June 3, 1999

Uncontrolled Potential Emissions (tons/year)		
Emissions Generating Activity		
Pollutant	General Tank 24 Building T100	TOTAL
PM	0.00	0.00
PM10	0.00	0.00
SO2	121.20	121.20
NOx	62.27	62.27
VOC	8.30	8.30
CO	79.90	79.90
total HAPs	109.81	109.81
worst case single HAP	*62.27	*62.27
Total emissions based on rated capacity at 8,760 hours/year.		
Controlled Potential Emissions (tons/year)		
Emissions Generating Activity		
Pollutant	General Tank 24 Building T100	TOTAL
PM	0.00	0.00
PM10	0.00	0.00
SO2	6.06	6.06
NOx	6.78	6.78
VOC	8.30	8.30
CO	79.90	79.90
total HAPs	54.62	54.62
worst case single HAP	(HCl) 47.54	(HCl) 47.54
Total emissions based on rated capacity at 8,760 hours/year, after control.		

Acetone, Methylene
Chloride, Phosgene,
Toluene, Triethylamine,
o Xylenes

Appendix A: Emissions Calculations

Source Name: Eli Lilly and Company, Tippecanoe Laboratories

Source Location: 1650 Lilly Road, Shadeland, Indiana 47902

County: Tippecanoe

Construction Permit No.: CP-157-11031-00006

SIC Code: 2834 & 2879

Permit Reviewer: Phillip Ritz/EVP

Eli Lilly and Company, Tippecanoe Laboratories, located in Shadeland, Indiana, has submitted an application for a new 4,000 gallon general tank in Building T100.

24871

Process Description:

The process vessels can be used in a variety of operations involved in pharmaceutical manufacturing. These operations are mainly batch in nature and include, but are not limited to: heating, cooling, distilling (atmospheric and vacuum), extracting, crystallizing, chemical synthesis, cryogenic service, and their associated operations.

The point source emissions from the process vessel may vent directly to the RTO, or they may first vent to scrubbers, process control condensers, vacuum sources, or through other process vessels before going to the RTO. If venting the process vessel to the RTO would cause safety concern, the process vessel may vent to an alternative pollution control device.

Emissions calculations for VOC point sources from the process vessel were performed by the applicant, using the equations found in the EPA Guideline for Control of Volatile Organic Compounds Emissions from Manufacture of Synthesized Pharmaceutical Products, EPA-450/2-78-029. The process vessel VOC emission estimates are based on a combination of the typical unit operations that are done to perform a process. The steps in the model process for tanks include charging, heating, tank evacuation with vacuum distillations, atmospheric distillations, centrifuging, and drying. For example, a distillation process can include a tank evacuation, a heating step, and a distillation step. For this process vessel, acetone (a non-regulated VOC) was used as the solvent in the emission calculations and a 365 day/year operating schedule was assumed to get a worst case potential emissions scenario. Although acetone is not a regulated VOC, the company has opted to calculate its emissions based on acetone. It is the highest volatility solvent representing a significant percentage of total current and anticipated solvent usage. Since solvents with vapor pressures as high as that of acetone are not always used in the processes, the assumption used in the calculations will generate a worst case estimate for the potential VOC emissions.

The calculations to estimate point source VOC emissions from the process tank assumes that the pollution control device is a condenser (exit gas temperature -150C). The VOC emissions leaving the condensers are calculated assuming ideal liquid and vapor in equilibrium at a given temperature and pressure. The condenser is used in the calculations because it provides the level of emission control that would be required to comply with 326 IAC 8-5-3. The actual VOC control device normally used on the tank will be either an existing condenser in series with the existing RTO, or the RTO alone. The RTO alone has been demonstrated to achieve in excess of 97 percent VOC reduction and therefore meets and exceeds the requirements of 326 IAC 8-5-3. Lilly would like to maintain the flexibility to use condensers during RTO malfunctions, provided the condensers can meet the requirements of 326 IAC 8-5-3 .

The proposed VOC potential to emit for the process vessel shown in the emission summary table is that required under 326 IAC 8-5-3. Actual emissions will be less than the potential to emit because the actual control device (i.e. the RTO with or without a precondenser) control efficiency exceeds that required by 326 IAC 8-5-3 (i.e. condenser with -150C exit gas temperature).

The fugitive VOC emissions estimate is based on an estimated fugitive source count for the process vessel and associated piping. Potential fugitive emissions were estimated by multiplying SOCMI factors (supplied by the applicant) for fugitive emission sources by the number of each type of source. The source count does not include any existing piping or fugitive sources that are not associated with the process vessel. The duration of exposure is assumed to be 24 hours/day, 7 days/week, and 52 weeks/year.

SO₂, NO_x, and CO emissions may also be emitted from the process vessel. There may be processes run where one or more of these pollutants is emitted from a gas evolving process step. Based on Lillys current knowledge of the processes run at Tippecanoe Laboratories, three different reactions were chosen to obtain an estimate of the potential SO₂, NO_x, and CO emissions. Each reaction is the highest known emitter of the respective pollutant it emits. There are many fewer processes that emit SO₂ NO_x, and CO than VOCs, therefore 100 lots/yr were used in the worst case potential emission calculation. This maximum emission rate is much higher than any one tank will emit by itself, but it is difficult to estimate how much of the emissions can be attributed to each individual tank. Therefore, the air emission inventory indicates that the entire building emission comes from each tank by itself. When summing the total emissions, this factor is taken into account by looking at the maximum emitting tank for building T100.

SO₂ emissions are controlled with caustic scrubbers. NO_x emissions are controlled with scrubbers also. CO emissions are vented to the RTOs. No emission limits on NO_x or CO are needed. However, a modification approval condition either requiring pollution controls or limiting emissions is needed to keep SO₂ emissions below the PSD/NSR Major Modification Threshold of 40 tpy.

Process Vessel Calculation Assumption:

1. Pure acetone equivalent VOC is used in all calculations.
2. The vessel contains perfectly mixed ideal liquid and vapor phases, and they are continuously in phase equilibrium.
3. The vapor leaving the vessel is assumed to have the same composition as the vapor in the tank's vapor space.
4. The streams leaving the condensers, where used, are calculated assuming liquid and vapor in equilibrium at the given temperature and pressure.
5. It is assumed that the amount of liquid being vaporized in the vessel is small compared to the total liquid volume. Therefore, the liquid composition in the vapor space can be assumed to be constant.
6. The control device is a condenser that will produce a condensate stream (per 326 IAC 8-5-3 for acetone) under all loading, or an equivalent device that will have the same control efficiency as this condenser.
7. VOC emissions are from the tanks themselves.
8. Nitrogen purge rate for inerting.
9. Charging into a tank.
10. Tanks.

21. It is assumed that during the time the tank is not performing a set of steps that it can be doing another operation that the 24 hour sweep will account for that operation's emissions, i.e., stirring, cooling.

22. "Per step" emissions are for performing the given step, or series of steps, once.

23. "Yearly" emissions are for performing the given step, or series of steps, once per day, 365 days per year.

24. Efficiencies are calculated according to the following formula:

Efficiency = 100% X ((Potential uncontrolled emissions)/(Potential uncontrolled emissions))

Calculation Nomenclature

a,b,c - Antoine coefficients

i - The ith component

K ideal - Vapor/liquid

LMPD - L

GENERAL ORGANIC SYNTHESIS PROCESS SUMMARY FOR 4,000 GALLON TANK

I-Emission steps considered in the model:

	VOC emissions, lb/step	Potential Uncontrolled	Potential
A. N2 inerting purge @ 5scfh	5.73	0.73	
B. Charge 4,000 gallon tank 2/3 full of Acetone	12.79	1.63	

C. Heat tank contents from 20C to 55C 39.79 0.77

Atmospheric Distillation

D. Heat from 20C to 56.3C 92.78 0.81

5 scfh N2 purge during distillation 2.29 0.24

Vacuum distillation

E. Evacuation 52.31 3.92

F. Sweep (0.5 scfm leak rate) 32.84 10.47

G. Depressurization from 2 to 1 atmospheres 16.08 3.21

II General Synthesis Model Emitting Steps (Point Source Emissions):

Step Description Step Duration lb/step lb/step

1a. Charge B 22.22 min. 12.79 1.63

Vacuum Distillation

1b. Evacuation E 52.31 3.92

1c. Sweep (0.5 scfm leak rate) F 24 hour 32.84 10.47

1c. Depressurize G 16.08 3.21

2a. Charge B 22.22 min. 12.79 1.63

Atmospheric Distillation

2b. Heat 20C to 56.3C D 92.78 0.81

2c. Sweep (5 scfh N2) 1 min. 2.29 0.24

2d. Depressurize G 16.08 3.21

3a. Charge B 22.22 min. 12.79 1.63

3b. Heat C 39.79 0.77

3c. Depressurize G 16.08 3.21

4a. Charge B 22.22 min. 12.79 1.63

4b. Nothing

4c. Depressurize G 16.08 3.21

5. 24 hour sweep A 24 hour 5.73 0.73

Total (lb/day) 341.19 36.28

Total (tons/yr) 62.27 6.62

*Potential controlled: control device is a vent condenser or equivalent controls meeting 326 IAC 8-5-3 requirements.

or in

ng ideal liquid

vessel is small when
sition and the volume of

an exit gas temperature of -150C
i equivalent control device that will

iselves, not ancillary existing equipment.
g purposes is 5 scfh.

ik is at 60 gallons per minute.

are charged 2/3 full of VOC for all tank sizes.

11. The tank is assumed to start each operation 2/3 full, except for "Charging" where the tank is empty at the start. The vapor space is assumed to be composed of gaseous N₂ in equilibrium with acetone vapor at the stated temperature.

12. The atmospheric distillation involves heating the tank contents (pure acetone) to its boiling point, then distilling over of the liquid volume. In the 4,000 gallon tank case, however, only 1/3 of the liquid volume is distilled. The time required to distill more solvent would push the possible process chains time over 24 hours.

13. During the atmospheric distillation, there are two condensers. The first is a process control condenser that produces an exit gas temperature of 23 0C(55 o F cooling water = 12.78 0C + 10 0C approach = 22.78 ~ 23 0C). The emissions from this condenser are listed in the potential uncontrolled column. The second is an emissions control condenser that produces an exit gas temperature of -15 0C, or a control device with the same control efficiency. The emissions from this condenser are listed in the potential controlled column.

14. There is a 5 scfh nitrogen purge during all atmospheric distillations.

15. "Evacuation" means evacuating the tank from atmospheric pressure down to above the vapor pressure of acetone at 20 0C.

16. The vacuum distillation inert leak rate is 0.5 scfm for all tank sizes. This is the average leak rate.

17. The vacuum distillation involves evacuating the tank to below acetone's vapor pressure at 200C, then distilling over

18. During the vacuum distillation, there is a control condenser that produces an exit gas temperature of -15 0C(55 o F cooling water = 12.78 0C + 10 0C approach = 22.78 ~ 23 0C). The emissions from this condenser are listed in the potential controlled column.

column. The second is an emissions control device that maintains a temperature of -15 °C, or a control device that maintains a temperature of -15 °C. Emissions from this condenser are listed in Table 19. The pressure transfer operation is to 2 atmospheres to force the liquid pressure is released from the tank.

20. There are no provisions for evacuation, or de-pressure operations.

ay,

ns - After control

d equilibrium constant

Log mean pressure difference (mm Hg)

L - Total moles in liquid phase (lb-mole)

L_i - Moles of component i in liquid phase (lb-mole)

M - Mass (lb)

M_i - Mass of component i (lb)

m - Mass rate (lb/hr)

m_i - Mass rate of component i (lb/hr)

MW - Molecular weight (lb/lb-mole)

MW_i - Molecular weight of component i (lb/lb-mole)

N or V - Total moles in vapor phase

n - Molar rate (lb-mole/hr)

N_i or V_i -

Controlled*

wn to 1 mmHg

sizes and vacuum levels.

ink from atmospheric pressure to
of the liquid volume.

re two condensers. The first is a process control
perature of 00C (-10 0C brine + 10 0C approach
ar are listed in the potential uncontrolled

ol condenser that produces an exit gas
 with the same control efficiency. The
 the allowable column.
 ition consists of pressuring-up the tank with nitrogen from 1
 uid out of the tank. When the tank is empty, this
 nk.
 cess condensers on the purge, charge, heat from 20 0C to 55 0C,
 ssurization steps. A condenser is not needed to perform these

b/lb-mole)

ase (lb-mole)

le/hr)

- Moles of component i in vapor phase (lb-mole)

n_i - Molar rate of component i (lb-mole/hr)

P or P_{total} - Total Pressure (mm Hg)

P_i - Partial pressure of component i (mm Hg)

p_0 - Vapor pressure (mm Hg)

p_{i0} - Vapor pressure of component i (mm Hg)

R - Ideal Gas Constant (10.73 ft³ psia/lb-mole °R)

T - Temperature in Kelvin (°K) or Rankine(°R)

t - Temperature in Celsius (°C) or Fahrenheit

V - Volume (ft³)

V or N - Total moles

V_i or N_i -

ieit (F)

in vapor phase (lb-mole)

- Moles of component i in vapor phase (lb-mole)

v - Volumetric rate (gpm for liquid, cfm for vapor or gas)

x i - Liquid mole fraction of component i

y i - Vapor mole fraction of component i

Z - Total moles entering condenser (lb-mole)

Z i - Total moles of component i entering condenser (lb-mole)

NOx Emission Calculations T100 Gen'I Tank 24

Appendix A, page 7 of 10

NOx

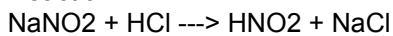
Basis: Worst case NOx emitting process

100 lots/yr for processes emitting NOx in T100.

Assumed all emissions can come from one tank or several tanks, but no more than a total of 100 lots/yr of any process that emits NOx will run in T100.

Since process stoichiometry is based on bulk facility building scale, scaled emissions from all processes to appropriate size of Gen'I Tank 24 (4,000 gallons).

Reaction 1:

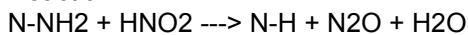


92.3 kg of NaNO₂ will be reacted with HCl, therefore:

$$92.3 \text{ kg NaNO}_2 (1000 \text{ g/1 kg})(1 \text{ mol/69 g NaNO}_2) = 1338 \text{ mol NaNO}_2$$

$$1338 \text{ mol NaNO}_2 \text{ yields } 1338 \text{ mol HNO}_2$$

Reaction 2:



Only half of the 1338 mol HNO₂ available reacts.

Therefore, 669 mol of N₂O are formed, 669 mol of HNO₂ remain.

Nitrous oxide (N₂O) is stable and inert.

Total NO₂ Formed:

669 mol NO ₂	----->	669 mol NO ₂
Formed from unreacted HNO ₂		NO ₂ evolved/lot

$$\begin{aligned} & \frac{669 \text{ mol NO}_2}{\text{lot}} \times \frac{46.01 \text{ g}}{\text{mol NO}_2} \times \frac{1 \text{ lb}}{454 \text{ g}} \times \frac{100 \text{ lots}}{\text{year}} \\ & = 6780 \frac{\text{lb NO}_x}{\text{lot}} \quad (\text{for a 2,000 gallon tank}) \end{aligned}$$

Potential to Emit

T100 Gen'I Tank 24 (4,000 gallons)

$$\frac{6,780 \text{ lb NO}_x}{\text{lot}} \times \frac{4,000 \text{ gallon}}{2,000 \text{ gallon}} \times \frac{1 \text{ ton}}{2,000 \text{ lbs}} = 6.78 \frac{\text{tons SO}_2}{\text{year}}$$